Version 1.0 – August 2012

STANDARDS ANALYSIS
BIOMEDICAL TECHNOLOGIES SECTOR
LUXEMBOURG

ANS/AN02

ILNAS
Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services

ANEC
AGENCE POUR LA NORMALISATION ET L'ÉCONOMIE DE LA CONNAISSANCE

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1. INTRODUCTION

To promote standardization in Luxembourg, ILNAS, *Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services*, has drawn up a national standardization strategy[1], which was approved by the Minister of the Economy and Foreign Trade on June 10th, 2010.

This national standardization strategy, directly related to the 2020 strategy of the European Union, is primarily based on the following guiding principle: "Setting standards means setting the market".
The goals of the standardization strategy are:

- to better support the national economy in terms of competitiveness, visibility and performance;
- to promote a homogenous standardization culture at national level;
- to improve the international position of the Grand Duchy of Luxembourg in standardization organizations;
- to launch an innovative and federative way for the national standardization process.

Thus, the act of participating in the standardization process does not only allow future standards to be anticipated but also allows the market to be guided by meeting its interests at any level. This strategy, including its operational objectives that are regularly updated, will be implemented through a sector-based economic approach and where national needs are identified.

To give new impetus to standardization in Luxembourg, this strategy is based on the five pillars mentioned hereafter, and detailed in Appendix 8.2:

- A sector-based standards approach as a support for the national economy,
- Innovation and research development in the frame of standardization,
- A sector-based development of ILNAS, Luxembourg's national standards body,
- Standardization training and public awareness,
- The creation and development of the Economic Interest Grouping "*Agence pour la normalisation et l'économie de la connaissance*" (ANEC).

Beginning in October 2010, ILNAS has been supported by the ANEC "*Agence pour la Normalisation et l'Economie de la Connaissance*" in implementing this strategy. The role of ANEC is to support the development of standardization activities at a national level and to promote the benefits of participating in standardization. Its missions are to create awareness, training, and monitoring in the field of standardization and applied research in order to support the competitiveness of companies in Luxembourg. Thus, ILNAS, with the help of ANEC, can effectively contribute to the economic diversification policy pursued by the government in the expertise niches of tomorrow.

In this context, ILNAS commissioned ANEC for the task of a standards analysis of the biomedical technologies sector. Indeed, in line with the priorities set by the government of the Grand Duchy of Luxembourg[2], this sector has been identified as a carrier for the national economy.
The biomedical technologies sector covers several areas: from pharmaceutical activities to medical devices and health informatics. Following discussions with public authorities, the scope was slightly reduced and while dentistry activities continue to be included, veterinary activities have been excluded. Finally, the biomedical technologies sector, as defined in this standards analysis, covers 5

[1] http://www.ilnas.public.lu/fr/publications/normalisation/etudes-nationales/ilnas-strategie-normalisation-2010-2020.pdf
[2] National program 2009-2014: http://www.gouvernement.lu/dossiers/sante/reforme-sante/index.html

subsectors: medical devices, medical equipment, medical services, diagnostics and eHealth (further detailed in chapter 5).

This standards analysis, which began in November 2011, consists of several steps as described in Figure 1.

Figure 1: Main steps of the standards analysis

In detail, the following actions have been achieved:

- Conduction of a standards watch of the targeted sector (inventory of standards published and under development at the European and international levels, identification of technical standardization committees),
- Targeting the national market of the related sector by identifying national stakeholders (public and private),
- Establishment of logical links between the national market, the different stakeholders and the results of the standards watch,
- Preparation of a final report of analysis and opportunities,
- Transfer of the standards knowledge acquired to various stakeholders.

As part of the standards analysis of the biomedical technologies sector, this report first describes the results of the standards watch by presenting the main European and international standardization technical committees that are currently working at developing or reviewing standards for this sector. Then, in order to bring the national stakeholders of the biomedical technologies sector into an active approach in standardization, logical links were established between the national market and the standards watch results.

From this analysis, potential interests for the national stakeholders, as well as opportunities for the sector as a whole, have been highlighted and are presented with a desire to inform and engage in general thinking. The main purposes of this analysis are to involve the stakeholders of the biomedical technologies sector into an integrated and innovative approach that promotes standardization in Luxembourg, and to support this sector in terms of competiveness, visibility and performance, while improving the international recognition of Luxembourg in the standardization field.

Note:
In accordance with ILNAS policy on participation in standardization technical committees, the term "standardization technical committee" is in this report a generic term that covers also the "technical committees", "subcommittees", "working groups", etc.

2. STANDARDIZATION

2.1. DEFINITIONS

❖ ILNAS:

This acronym designates the "*Institut Luxembourgeois de la Normalisation, de l'Accréditation, de la Sécurité et qualité des produits et services*". ILNAS, an administration under the authority of the Minister of the Economy and Foreign Trade, was created by the law of May 20th, 2008, and began its activities on June 1st, 2008.

❖ OLN:

This acronym designates the "*Organisme Luxembourgeois de Normalisation*", an ILNAS department and which, according to the law of May 20th, 2008, fulfills the ILNAS missions as a national standardization organization. A national standards body recognized at national level is eligible to be a national member of the corresponding international and European standards organizations.

❖ STANDARDIZATION:

Standardization is a VOLUNTARY, CONSENSUS-driven activity, carried out by and for the interested parties themselves, based on openness and transparency, within independent and recognized standards organizations, leading to the adoption of standards with which compliance is voluntary.[3] It is the activity of establishing with regard to actual or potential problems, provision for common and repeated use, aimed at the achievement of the optimum degree of order in a given context.[4]

❖ STANDARD:

A standard is a document established by consensus and approved by a recognized body and that provides applicable guidelines for activities. Standards are for common and repeated used rules, guidelines or characteristics for products or related processes and production methods for which compliance is not mandatory.[5] They have a national, regional or international concern. Standards are created by bringing together all interested parties, such as manufacturers, consumers and regulators of a particular material, product, process or service. All parties benefit from standardization. Several categories of standards exist: core standards, standards of analysis and testing, standards of specifications, methodological standards, etc.

❖ STANDARDS BODY:

A standards body can be defined as a standardizing body recognized at the national, regional or international level that has as its principal function the preparation, approval or adoption of standards that are made available to the public.[6]

In this report, a distinction has been made between formal standards bodies (e.g. CEN or ISO) and non-formal standards bodies (e.g. HL7 or DICOM).

[3] Official Journal of the European Communities 2000/C141/01
[4] Based on the definition proposed in the standard EN 45020:2006: Standardization and related activities – General vocabulary
[5] Based on the definition proposed in the standard EN 45020:2006: Standardization and related activities – General vocabulary
[6] Based on the definition proposed in the standard EN 45020:2006: Standardization and related activities – General vocabulary

❖ STANDARDIZATION TECHNICAL COMITTEE:

A technical decision-making body with a precise title, scope and work program, within a European and/or international standardization organism, essentially to manage the preparation of deliverables as standards in accordance with an agreed upon business plan.[7]

❖ CEN WORKSHOP AGREEMENT:

A CEN Workshop Agreement (CWA) is a standardization document, developed in a CEN Workshop. The latter is open to the direct participation of anyone with an interest in the development of the agreement. There is no geographical limit on participation and hence participants may be from outside of Europe. The development of a CWA is fast and flexible. It does not have the status of a European standard, and there is no obligation for the national standards bodies to adopt it as national standards.[8]

❖ NATIONAL MIRROR COMMITTEE:

A national mirror committee is a national structure to European or international technical committees, ensuring, for example, the formulation of coherent national positions as a first round of consensus finding.[9]

2.2. STANDARDIZATION OBJECTIVES

Standardization is an efficient economical tool offering the possibility to pursue various objectives, such as:

- Management of the diversity,
- Convenience of use,
- Compatibility,
- Interchangeability,
- Health,
- Security,
- Environmental protection,
- Product protection,
- Mutual understanding,
- Economic performance,
- Trade,
- Etc.

The standardization principles are:

- Voluntary: standardization is open to all and is based on voluntary involvement of all the actors of the market.
- Consensus: a standard is approved by consensus; all the positions of all the participants are taken into account (manufacturers, vendors and users, consumer groups, testing laboratories, governments, engineering professions, research organizations, etc.).
- Industry wide: a standard is developed to offer global solutions to satisfy industries and customers all around the world.

[7] Based on the information available on the CEN website/BOSS
[8] Based on the information available on the CEN website/CEN Workshop Agreements
[9] Based on the information available on the CEN website/Glossary

2.3. STANDARDIZATION LANDSCAPE

In Europe, the 3 recognized European Standards Organizations (ESO) are:

- the European Committee for Standardization (**CEN**),
- the European Committee for Electrotechnical Standardization (**CENELEC**),
- the European Telecommunications Standards Institute (**ETSI**).

At the international level, the two recognized Standards Organizations are:

- the International Organization for Standardization (**ISO**),
- the International Electrotechnical Commission (**IEC**).

The standardization frame allows cooperation between the standardization organizations at the same level, but also at different levels, on the same topics:

- CENELEC and IEC are specialized in electrotechnical standards,
- ETSI is focused on telecommunications standards,
- CEN and ISO are in charge of the other types of standards in the other sectors.

Table 1 presents the main characteristics of the European and international standards bodies.

Table 1: Characteristics of European and international standards organizations

European and International Standards Bodies		Date of creation	Number of Members	Number of published standards
ISO	International Organization for Standardization	1946	163	19 023
IEC	International Electrotechnical Commission	1906	82	6 513
CEN	European Committee for Standardization	1961	32	14 498
CENELEC	European Committee for Electrotechnical Standardization	1973	32	6 529
ETSI	European Telecommunications Standards Institute	1988	739* (62 countries)	29 854

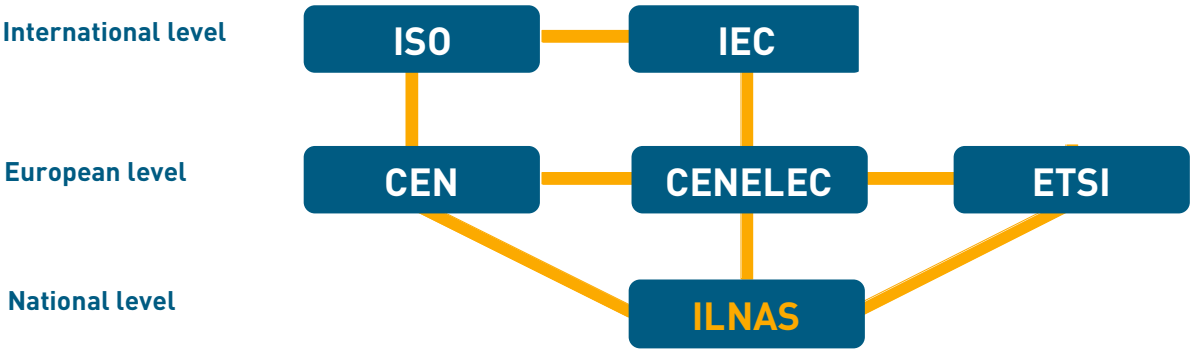
Source: Websites of organizations – 05.07.2012

*Note: ETSI has a specific way of working compared to the other recognized organizations, as it works through the direct participation of industry stakeholders.

From a national perspective, one or several standardization bodies protect national interests from within the European and international standardization organizations. In Luxembourg, ILNAS – the only official national standards organization – is a member of the European and international standards organizations CEN, CENELEC, ISO, IEC and ETSI.

Several bridges exist between the national, European and international standardization bodies in order to facilitate the collaboration and coordination of the standardization work on the different fields (Figure 2).

Figure 2: Interactions between the standardization organizations



A strong collaboration exists between the European and international standards bodies. To increase transparency in the work and avoid the duplication of standards, the Vienna Agreement was concluded in 1991 between ISO and CEN. This agreement is based on the following guiding principles:

- Primacy of international standards and implementation of ISO Standards at European level (EN ISO),
- Work at European level (CEN) if there is no interest at international level (ISO),
- Notifications of the standardization documents for approval between the two organizations.

Similarly, the Dresden Agreement was concluded in 1996 between IEC and CENELEC with the aim of developing intensive consultations in the electrotechnical field. This agreement is based on the following guiding principles:

- Development of all new standardization projects by IEC (as much as possible),
- Work at European level (CENELEC) if there is no interest at international level (IEC),
- Ballots for documents made in parallel at IEC and CENELEC.

Under both agreements, approximately 55% of all European standards ratified by CEN, and about 70% of those ratified by CENELEC, are now technically equivalent or identical to ISO or IEC standards; in that respect, the European and international organizations do not duplicate work.

Agreements also exist between the standards bodies to facilitate their cooperation. The two conventions established between ISO and IEC allow the creation of joint technical committees. Similarly, the cooperation between CEN and CENELEC aims to create a European standardization system that is open, flexible and dynamic, such as the CEN/CLC Joint Working Group on Active Implantable Medical Devices.

2.4. STANDARDS DEVELOPMENT

Developing a standard is characterized by four main steps:

- Proposal: following an identified need, a party proposes a preliminary draft,
- Study and preparation: a working group studies the draft and prepares the standard draft,
- Public Inquiry and Approval: the standard draft goes into public consultation and is subject to approval in a second step,
- Publication: the ratified standard is published by the standards body.

At each stage, a validation of all participating members of the standardization technical committee is required. This is done automatically as a vote; however, the rules of the vote differ between the European and international level as outlined in Table 2 below.

Table 2: Voting rules at European and international levels

Organization	Members	Method of adopting standards	Integration into the collections of national standards
International ISO and IEC	National bodies from countries members of ISO (163) and IEC (82)	1 country = 1 voice	Voluntary
European CEN and CENELEC	National bodies from the EU and EFTA*countries (33)	Weighted Vote (Treaty of Nice)	Required: countries must eliminate conflicting provisions from their collections

* EFTA: « European Free Trade Association » whose current members are Norway, Switzerland, Iceland and Liechtenstein.

The weighted vote is defined by the Treaty of Nice, which was signed in 2001 by the EU Member States and fixes the distribution of the voices for the European Union Council as show in Table 3.

Table 3: Distribution of the weighted votes throughout the European Member States

Country	Weighting of votes
France, Germany, Italy, Turkey, United Kingdom	**29**
Poland, Spain	**27**
Romania	**14**
Netherlands	**13**
Belgium, Czech Republic, Greece, Hungary, Portugal	**12**
Austria, Bulgaria, Sweden, Switzerland	**10**
Croatia, Denmark, Finland, Ireland, Lithuania, Norway, Slovakia	**7**
Cyprus, Estonia, Former Yugoslav Republic of Macedonia, Latvia, Luxembourg, Slovenia	**4**
Iceland, Malta	**3**

Source: Internal regulation CEN/CENELEC – Part 2 – Annex D

Other particularity at the European level, the European standards approved shall be implemented identical in technical content and presentation and with no restrictions for application by each national member. This implies enforcing the new standard through publication and withdrawing all conflicting standards already in place at the national level in an average of 6 months. The new European standard then takes the status of national standard.

3. CONTEXT OF THE BIOMEDICAL TECHNOLOGIES SECTOR

3.1. DEFINITION AND ISSUES OF THE BIOMEDICAL TECHNOLOGIES SECTOR

As part of the health domain, biomedical technologies are covered globally by the definition of health technology provided by the World Health Organization (WHO).[10] According to the WHO, it refers to the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life. These technologies equip healthcare providers with the tools necessary for effective and efficient prevention, diagnosis and treatment. The WHO also recognizes the important role of biomedical technologies in the functioning of an efficient health system.[11]

By covering a broad spectrum of activities, as for example medical devices or eHealth applications, the biomedical technologies sector has become an important topic in recent years, at the international, European or national levels. Major challenges and issues will have to be faced in the coming years by the international community in order to reinforce the healthcare system and the quality of life. Biomedical technologies constitute a key driver to achieving these objectives.

Talking about the health in general, the international context shows a gradual improvement in life expectancy and, at the same time, the ageing of the population. In parallel, a steady increase of healthcare expenditures has also been observed. In 2009, countries in the Organisation for Economic Co-operation and Development (OECD) devoted 9.6% of their Gross Domestic Product (GDP) to health spending, which constitutes a sharp increase from the 8.8% seen in 2008.[12]
Under these conditions, policymakers and leaders have to adjust healthcare systems in order to be able to correctly address these issues. Given the pressures caused by increasing expenditures, the demographic challenges of an ageing population, and an increasing demand for quality healthcare services, the improvement of healthcare systems is of vital importance. Innovations powered by biomedical technologies are seen as being able to provide potential solutions to improve the quality and the efficiency of healthcare systems. Furthermore, biomedical technologies are often considered to be a provider of quality employment. In Europe, over 500 000 people are employed by 22 500 medical technology companies, of which 80% are small and medium-sized enterprises.[13]

At the European level, actions regarding the health sector and, more precisely, the biomedical technologies, are based on the EU Health Strategy, "Together for Health: A Strategic Approach for the EU 2008-2013" [14], from the EU Commission. Health research is stated as a priority of major importance for the European Union. One of the challenges set out in the EU Strategy is to support the development of new technologies dedicated to the health sector. To maintain and reinforce this strategy, the Commission adopted on November 9th, 2011 a legislative proposal for the third multi-

[10] World Health Assembly resolution WHA60. May 29th, 2007: http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf
[11] Development of medical device policies - WHO Medical device technical series, 2011: http://whqlibdoc.who.int/publications/2011/9789241501637_eng.pdf
[12] OECD, "Health at a Glance: Europe 2011", 2011: http://www.oecd.org/dataoecd/6/28/49105858.pdf
[13] EUCOMED, "The medical technology industry in Europe", 2011: http://www.eucomed.org/uploads/Modules/Publications/110527_the_medical_technology_industry_in_europe.pdf
[14] Commission of the European Communities, White Paper "Together for Health: A Strategic Approach for the EU 2008-2013", 2007 [COM/2007/630]: http://ec.europa.eu/health-eu/doc/whitepaper_en.pdf

annual program: Health for Growth (2014-2020).[15] This new program was drafted to pursue the efforts to help EU countries respond to economic and demographic challenges facing their healthcare systems.

On the national side, Luxembourg has already started in 2010 to reform its national health system. The strategic orientations to be handled are[16]:

- Maintaining the solidarity of the public healthcare system and develop the quality and complementarity of the coordinated networks,
- Control the evolution of the overall cost of health insurance and ensure the sustainability of the healthcare system,
- Create a data management system that meets the criteria of comprehensiveness, transparency, reliability, standardization, comparability and exchangeability.

Approved in July 2010 by the Government Council, the law regarding the reform of the healthcare system was approved by the *Chambre des députés* in December 17th, 2010.[17] This reform should progressively turn the healthcare system of Luxembourg towards proactive medicine by developing a more personalized and patient-centered approach. For this ambitious goal to be successful, Luxembourg relies on the biomedical technologies sector. Indeed, the idea is to combine innovative sciences to health in order to develop a pioneering healthcare system more tailored to patients through new tools and information technologies.[18]

The Government of Luxembourg identified health technologies as key innovation drivers that are able to reinforce national competitiveness and the country's economy through an innovative healthcare system. Indeed, the health sector, and more specifically, biomedical technologies, constitutes in Luxembourg a significant economic motor in constant progress. During the period 2000-2010, the employment rate of the "*services de santé et d'action sociale*" sector registered a non-negligible increase of the overall national employment from 6.3% to 8.3%.[19] And by encouraging and supporting the development of the biomedical technologies sector, it is progressively moving towards activities with higher added value.

The major project initiated by the Government of Luxembourg in June 2008 to develop specific expertise in the field of molecular medicine is a concrete example of the national actions taken in favor of the biomedical technologies sector. This initiative operates in close collaboration with 3 renowned American Research Institutes and creates 2 key infrastructures: the Integrated BioBank of Luxembourg (IBBL) and the Luxembourg Centre for Systems Biomedicine (LCSB).

The Government of Luxembourg sees eHealth as a sustainable solution to improve the healthcare system. In 2006, the national eHealth plan[20] was adopted with the objective of facilitating the exchange of health-related data between healthcare professionals in order to improve the quality and performance of healthcare and to better handle expenditures. Developments are currently underway to create an interoperability platform and a dedicated agency for eHealth services in Luxembourg: *Agence eSanté*.[21]

[15] European Commission, Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme, the third multi-annual program of EU action in the field of health for the period 2014-2020, 2011 [COM/2011/709]: http://ec.europa.eu/health/programme/docs/prop_prog2014_en.pdf
[16] National program 2009-2014: http://www.gouvernement.lu/dossiers/sante/reforme-sante/index.html
[17] Loi du 17 décembre 2010 portant réforme du système de soins de santé et modifiant: 1. le Code de la sécurité sociale; 2. la loi modifiée du 28 août 1998 sur les établissements hospitaliers: http://www.legilux.public.lu/leg/a/archives/2010/0242/2010A4042A.html
[18] HealthCast Study, PricewaterhouseCoopers Luxembourg, 2010: http://www.pwc.com/healthcast
[19] STATEC, National Accounts, E2310, Employment per sector of activity for 1995-2011: http://www.statistiques.public.lu
[20] Plan d'action eSanté du Luxembourg, 2006 : http://www.sante.public.lu/fr/systeme-sante/programme-esante/esante_plan_actions_detail_060704_060926.pdf
[21] http://www.sante.public.lu/fr/actualites/2011/12/agence-esante/index.html

3.2. STANDARDS CONTEXT OF THE BIOMEDICAL TECHNOLOGIES SECTOR

The biomedical technologies sector is strongly impacted by the standardization activities both at the international and European level. Indeed, one of the major aims of standardization in this sector is to ensure a high degree of patient health and safety. In Europe, the main EU standards are reinforced by dedicated EU Directives; thus, they have to be fully integrated and understood by the standards users. In addition, as in other sectors, standardization supports the implementation of public health policies; from the industry's side, this facilitates access to the international market.

The healthcare domain is used to participating in standardization activities as is, the biomedical technologies sector. The objectives of these standards are various, as for example they:

- Ensure patient safety and improve healthcare provision,
- Provide industrial guidelines for the design of medical devices and instruments,
- Guide biomedical laboratories and research institutes on the best practices to conduct diagnoses, analysis following basic safety requirements,
- Simplify and harmonize the used terminology in the biomedical technologies sector,
- Support the development of new technologies, as in the eHealth domain,
- Etc.

At a European level, as previously mentioned, standardization activities are strongly linked to a series of European directives. Indeed, through these directives the European Commission defines essential requirements that goods and services must meet when they are placed on the market.
Based on these directives, European standards bodies have the task of drawing up the corresponding technical specifications that meet the essential requirements of the directives, compliance with which will provide a presumption of conformity with the essential requirements. Such specifications are referred to as "harmonized standards". As explained, they are elaborated on the basis of a request from the European Commission or EFTA Secretariat through mandates to a recognized European Standards Organization, such as the CEN, CENELEC, or ETSI. This is known as the "New Approach".

Following the New Approach, the harmonization of the requirements relating especially to the safety and performance of medical devices started in Europe in the 1990s.
The core legal framework of the harmonized standards developed in the biomedical technologies sector consists of 3 EU Directives:

- Active Implantable Medical Devices (90/385/EEC) regarding active implantable medical devices,
- Medical Devices (93/42/EEC) regarding medical devices, and
- In Vitro Diagnostic Medical Devices (98/79/EC) regarding in vitro diagnostic medical devices.

Several modifications have been implemented to complete these 3 directives, including the technical revision provided by Directive 2007/47/EC.

Various collaborative initiatives also exist in the healthcare domain at the European and international level in order to encourage the harmonization of standards.

In Europe, a specific board of experts dedicated to the healthcare sector exists between the CEN and the CENELEC. This is the CEN-CENELEC Advisory Board for Healthcare Standards (ABHS). One of the main objectives of this board, through its different task forces, is to provide to European policymakers advice based on the latest developments in the European healthcare landscape. Created in December 2005, it replaces the former CEN Healthcare Forum (CHeF). The ABHS is involved in various issues affecting healthcare standardization, such as the environmental aspects influencing the sector, the need for legislation concerning global harmonization of medical devices, risk management for medical devices, or eHealth standardization activities.

The missions of the ABHS are to:

- Ensure the coordination of the relevant CEN Technical Committees,
- Solve problems that are common across the healthcare committees,
- Analyze of the latest developments affecting healthcare standardization,
- Manage CEN healthcare actions that come from the European Commission/European Free Trade Association (EFTA),
- Ensure that useful information and advice is passed on to the CEN Technical Board and other committees.

Many different healthcare sector stakeholders participate in ABHS activities including National Standards Bodies, National Health Authorities, international and European associations, etc. Membership to the ABHS is free and open to those who want to provide input into European healthcare standardization.

At the international level, the Global Harmonization Task Force (GHTF), created in 1992, also tries to respond to the growing need for international harmonization in the regulation of medical devices. GHTF is a forum for national regulatory authorities and industry representatives meant to promote an international convergence in regulatory requirements and practices to ensure the safety, effectiveness and quality of medical devices; to promote technological innovation; and to facilitate international trade. To achieve this purpose, harmonized documents on basic regulatory practices are published and disseminated. Three liaison body members participate to this group: International Organization for Standardization (ISO), International Electrotechnical Commission (IEC) and Asian Harmonization Working Party (AHWP).
Another group of experts that is interesting to mention and that is acting at an international level is the WHO Expert Committee on Biological Standardization. It establishes detailed recommendations and guidelines for the manufacturing, licensing, and control of blood products, cell regulators, vaccines, and related in vitro diagnostic tests, like for example the WHO International Biological Reference Preparations. Members of this committee are experts from national agencies, the academic sector, research institutes, public health bodies, and the private sector.

At the national level, 7 national delegates are currently registered among the Luxembourg's national standards body, ILNAS, and are actively participating in 10 of the selected technical committees:

- CEN/TC 102 Sterilizers for medical purposes
- CEN/TC 215 Respiratory and anaesthetic equipment
- CEN/TC 332 Laboratory equipment
- ISO/TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use
- ISO/TC 84 Devices for administration of medicinal products and intravascular catheters
- ISO/TC 121 Anaesthetic and respiratory equipment
- ISO/TC 198 Sterilization of health care products
- ISO/TC 210 Quality management and corresponding general aspects for medical devices
- ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems
- ISO/TC 215 Healthcare informatics

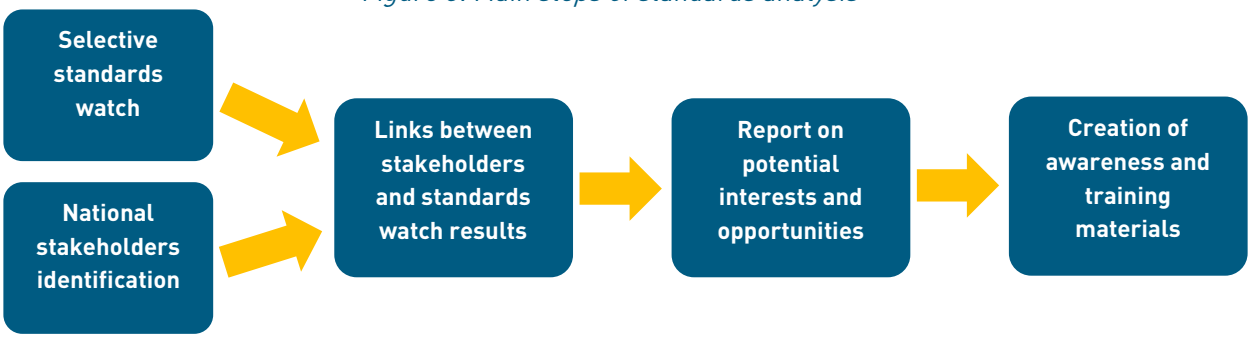
Based on the national standardization strategy,[22] ILNAS launched several actions in order to promote standardization in Luxembourg and to extend the participation to technical committees either at the European or international level, especially in the biomedical technologies sector.

[22] http://www.ilnas.public.lu/fr/publications/normalisation/etudes-nationales/

4. METHODOLOGY OF THE STANDARDS ANALYSIS

In order to meet the national standardization strategy issues described in the previous chapter, a standards analysis was carried on and is presented in this report. Different steps were followed and are illustrated by Figure 3 below.

Figure 3: Main steps of standards analysis



4.1. SELECTIVE STANDARDS WATCH

A standards watch was carried on in order to identify the standardization technical committees of potential interests for the national stakeholders in the biomedical technologies sector. These technical committees are either from formal standards bodies (for example, CEN, CENELEC, ISO or IEC) or managed from non-formal standards bodies (e.g. HL7, DICOM).
The different stages processed to carry on the watch analysis are described below.

❖ Stage 1: Identification of the standardization technical committees in relation with the biomedical technologies sector

The objective of this stage is to identify the standardization technical committees in relation to the biomedical technologies sector. The method used consists of identifying the sources of information available, applying the relevant research criteria and recording interesting and useful data. As mentioned before, the search focused not only on formal standards bodies but was opened to non-formal standards bodies.

Information sources
As stated in the following information sources were used.

Table 4: Information sources used

Source	Level	Designation	Website
Formal standards body	European	CEN – European Committee for Standardization	www.cen.eu
		CENELEC – European Committee for Electrotechnical Standardization	www.cenelec.eu
		ETSI – European Telecommunication Standards Institute	www.etsi.eu
	International	ISO – International Organization for Standardization	www.iso.org
	International	IEC – International Electrotechnical Commission	www.iec.ch
Intergovernmental public-private partnership organization	International	ITU-T – International Telecommunication Union	www.itu.int
Non-formal standards body	International	DICOM - Digital imaging and communication in medicine	www.medical.nema.org
		HL7 - Health Level Seven International	www.hl7.com
Standardization mandates	European	Database of standardization mandates. When the European Commission identifies a particular need of standards to support and implement its policy, it directly mandates the European standardization bodies (CEN-CENELEC-ETSI) to develop new standards.	www.ec.europa.eu
Legislation	European	European directives and regulations – The "new approach" encourages the use of harmonized standards, listed in the appendix of each directive. These standards give those who apply a presumption of conformity to the Directive "new approach".	www.ec.europa.eu www.newapproach.org
	National	National laws and regulations	www.legilux.lu
Sector news	International	World Health Organization (WHO) Organisation for Economic Co-operation and Development (OECD) United Nations Development Programme (UNDP), etc.	www.who.int www.oecd.org www.undp.org
	European	Publications and communications of the European Commission (DG SANCO), National Standards Bodies (AFNOR, DIN, BSI, ILNAS, etc.)	
	National	Publications and communications of the Ministry of Health, GIE Luxinnovation–BioHealth Cluster, etc.	www.ms.public.lu www.biohealthcluster.lu

Research criteria

Table 5 lists the different research criteria used.

Table 5: Research criteria

Research Criteria	Source	Explanation
ICS Code	Formal standards bodies	ICS means International Classification for Standards. At the publication stage, one or more ICS codes are assigned to the standard by the technical committee that drafted it. The international classification aims to classify standards according to codes common to all national, European and international standards bodies. However, the ICS codes being assigned to published standards (or draft standards of advanced stage) do not allow for the identification of standards currently under development in newly established technical committees.
TC Number	Formal standards bodies	TC means Technical Committee. The existing technical committees in the different standards bodies have been reviewed and all those related to the biomedical technologies sector have been identified.
Keywords (web research)	Non-formal standards bodies Standardization Mandates Legislation Sector news	A search was conducted on different websites using keywords such as standards, biomedical, biomedicine, health, etc. Moreover, an analysis of national and international publications related to the sector was conducted.

Records

Based on applied research criteria, the following data has been recorded, when available:

- Standards body (either formal or non-formal),
- Technical Committee number and designation,
- Number of member countries (only participating countries),
- Published standards,
- Standards under development,
- Link with one or more European directives,
- Link with one or more European standardization mandates.

In addition, to facilitate the view and the understanding of the watch results, the biomedical technologies sector was divided into subsectors (see Chapter 5). Finally, the overall standardization technical committees identified were classified according these subsectors.

❖ Stage 2: Selection of the most active standardization technical committees in terms of being current, dynamic and strategic

This stage gives a selective character to the standards watch in the biomedical technologies sector. The purpose is to keep only the standardization technical committees that could be of potential interest for future national delegates willing to contribute to the standardization and also to be in line with the news and developments of the sector. Therefore, the most active standardization technical committees have been selected based on specific criteria.

Selection criteria

Table 6 gives the list of the different criteria used to realize the selection of the most active technical committees.

Table 6: Criteria applied to select the technical committees

Selection criteria	Explanation
Technical committee creation date	A recent creation indicates a new need of standards related to news or regulation.
Number of participating countries	If a technical committee has a large number of participating countries, this reflects a strong mobilization around an important subject.
Standards under development	Standards under development are very concrete elements of participation in standardization. Further study of on-going standards will determine those that are strategic for the biomedical technology sector in general.
Link with one or more European directives	The "new approach" directives encourage the use of harmonized standards published in the Official Journal of the EU. These standards give those who apply them, a presumption of conformity with essential requirements of the directive. The link between legislation and standardization is then obvious since the standards applied allow for complying with legal requirements.

Records

When possible, additional data has been recorded for the technical committees remaining after the application of the selection criteria:

- Secretariat and secretary,
- Chairperson,
- Organizations in liaison,
- Business Plan,
- Comments
- Etc.

❖ Stage 3: Presentation of the results using identification cards for each standardization technical committees

Identification cards (ID-Cards) were designed in order to present each selected technical committee through a simple and quick view. However, if a large majority of the technical committees identified are from formal standards bodies, some of them were coming from non-formal standards bodies. As the information available is slightly different between these types of organizations, two different templates were designed and used to present the watch results.

The template used for the technical committees of the formal standards bodies is presented below.

<table>
<tr><th colspan="4">General Information</th></tr>
<tr><td>Creation Date</td><td></td><td colspan="2" rowspan="5">Title of the TC
(e.g. ISO/TC XXX)</td></tr>
<tr><td>Secretariat</td><td></td></tr>
<tr><td>Secretary</td><td></td></tr>
<tr><td>Chairperson</td><td></td></tr>
<tr><td>Organizations in liaison</td><td></td></tr>
<tr><td>Subcommittees / Working groups</td><td colspan="3"></td></tr>
<tr><td>Participating Members
  </td><td></td><td>Observing Members
  </td><td></td></tr>
<tr><td>Total</td><td></td><td>Total</td><td></td></tr>
<tr><td>Participation of Luxembourg</td><td></td><td>National delegates</td><td></td></tr>
<tr><td>European Directives</td><td colspan="3"></td></tr>
<tr><td>Standardization Mandates</td><td colspan="3"></td></tr>
<tr><th colspan="4">Business Plan</th></tr>
<tr><td>Version</td><td colspan="3"></td></tr>
<tr><td>Scope</td><td colspan="3"></td></tr>
<tr><td>Executive summary</td><td colspan="3"></td></tr>
<tr><th colspan="4">Work Program</th></tr>
<tr><td>Published standards</td><td colspan="3">number</td></tr>
<tr><td rowspan="2">Standards under development</td><td colspan="3">number</td></tr>
<tr><td colspan="3">➢</td></tr>
<tr><th colspan="4">Comments</th></tr>
<tr><td colspan="4"></td></tr>
</table>

Note: Details for the European Directives and Standardization Mandates categories are only available for the European Standardization Technical Committees.

The other template prepared to present the standardization activities of non-formal standards bodies in the biomedical technologies sector is presented below.

General Information		
Creation Date		**Title of the Project**
Chairperson		
Organization Members		
Website		
Scope		
Executive summary		
Structure		
Publications		
Comments		

4.2. STAKEHOLDERS OF THE NATIONAL BIOMEDICAL TECHNOLOGIES SECTOR

In parallel to the standards watch, the identification of national private and public stakeholders representing the entire biomedical technologies sector in Luxembourg was conducted. This national panorama of the biomedical technologies sector proposes a view of the situation based on the experience and expertise of the ILNAS. It reflects the situation at a certain moment from a certain point of view and is not intended to be exhaustive but tries to be as complete as possible. If necessary, it would be adjusted following the comments received after the release of this report.

The overall national stakeholders of the biomedical technologies sector have been reviewed. Based on the available information (documentation, internet websites, conferences, etc.), the analysis was carried out by seeking to identify the maximum number of relationships, connections and interactions between the different national stakeholders.

Then, according to their activities and objectives, they were allocated to different categories in order to draw a full and complete picture of this sector in Luxembourg. This proposed categorization was designed to facilitate the standards analysis. By grouping the different stakeholders into categories, it should facilitate the analysis, as stakeholders of a same category should have similar potential interests in participating to standardization activities. Then, connections between the biomedical technologies subsectors and the categories of stakeholders should be simplified.

4.3. INTERESTS AND OPPORTUNITIES FOR THE NATIONAL MARKET

After compiling the selected technical committees in relation to the biomedical technologies into subsectors and categorized the different stakeholders, an analysis of the potential interests for the national stakeholders to participate to the standardization work was carried on.

This step consists in identifying, for each stakeholder category, the potential interests to follow and participate in the standardization technical committees. In practice, it links a category of stakeholders with biomedical technologies subsectors as they were defined in the initial stage of the selective standards watch according to their potential interests.

❖ Stage 1: Definition of the potential interests for stakeholders

The potential interests defined were the following:

◆ **Information**	Thanks to the participation to a standardization technical committee, the stakeholders are informed about the last standardization developments relating to their activities, thus allowing them to identify potential future impacts and to anticipate the consequences.
■ **Performance**	Through participation in standardization activities within a technical committee, stakeholders contribute to the increase of their performance in particular: Development of new competencies due to contact with other professionals and experts of the sector (networking); Information on the directions taken by other states or other entities (benchmarking); Translation of the innovations into future rules (knowledge codification); Anticipation of the obligation to comply with European regulatory requirements.

❖ **Services**	The follow-up of standards developments offers in some cases the opportunity for stakeholders to develop new services in line with their activities.
☐ **Projects**	Research projects directly linked to standardization or involving standards in order to codify the acquired knowledge are regularly launched. Stakeholders can access useful information in the framework of a future call for tenders and benefit from specific support to get involved into projects.
O Training	Thanks to the knowledge of standards and process, stakeholders have solid and reliable elements to update, improve or develop training in the biomedical technologies sector.
$ Investments	Stakeholders could have an interest in investing in a new technology or concept.

❖ Stage 2: Matrix of the potential interests and the biomedical technologies subsectors

Then, for each stakeholder category, a specific matrix was realized to cross the biomedical technologies subsectors classifying the selected standardization committees with the potential interests of the national stakeholders (Figure 4).

Figure 4: Example of a specific matrix of standards analysis

Stakeholder Category (e.g. Public Institutions)	Subsector 1 Medical devices (10 TCs)	Subsector 2 Medical equipment (11 TCs)	Subsector 3 Medical services (5 TCs)	Subsector 4 Diagnostics (9 TCs)	Subsector 5 eHealth (7 TCs)
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services					
Projects					
Training					
Investments	X	X	X	X	X

The main objective of this approach is to establish a relationship between a specific stakeholder category and some biomedical technologies subsectors. This link is made by suggesting potential interests specific to each stakeholder category according to particular subsectors.

This information could be interesting for them in order, for example, to increase their competitiveness or to facilitate their European and international exchanges

❖ Stage 3: Definition of the opportunities for the national market

Finally, from this relationship between the stakeholder categories and the technical committee subsectors, opportunities for the national market have been identified. These opportunities are based on the potential interests common to all stakeholder categories. However, when interesting, some opportunities could also be dedicated to only a specific category of stakeholders.

These opportunities should be seen by the national market as a series of proposals in order to go further and to engage future actions to take advantage of the standardization.

5. RESULTS OF THE STANDARDS ANALYSIS

5.1. SELECTIVE STANDARDS WATCH

The standards watch of the biomedical technologies sector has identified 121 standardization technical committees (European and International), which are all listed in a database and presented in the Appendix 8.5. By applying the selection criteria detailed in the previous chapter, 42 technical committees were identified as interesting in terms of being "current, dynamic and strategic for the biomedical technologies sector".
In the framework of the standards watch and in particular to establish links between the national market of the biomedical technologies sector and the watch work results, the technical committees were classified into 5 subsectors, as shown in Table 7.

Table 7: Definition of the biomedical technologies subsectors

Subsector 1 - Medical devices sector	Based on the definition found in EU Directive 2007/47/EC, a medical device encompasses "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application". However, this definition is relatively large in scope. In order to process to a more detailed categorization of the technical committees, this subsector was slightly reduced by extracting the medical equipment that will constitute another subsector (subsector 2). So, the subsector 1 dedicated to medical devices contains, among other things, medical instruments and implantable medical devices.
Subsector 2 - Medical equipment sector	Extracted from the medical devices sector and based on the ISO standard 13485:2003, medical equipment is mainly "designed to aid in the diagnosis, monitoring or treatment of medical conditions. It generally groups all the medical devices that use electricity or other sources of power to make it function".
Subsector 3 - Medical services sector	The healthcare services sector concerns the provision and supply of health services. It encompasses all services delivered and performed by health personnel or other people under the supervision of these personnel to promote, maintain, improve, or restore the general mental or physical well-being of the patient. A remark as to be made at this level on the medical services subsector. European legislation currently under process details the framework for the development of European standards or European standardization deliverables for services. This would have a direct impact on the standardization activities in the health sector, as it states that they have to fully respect the distribution of competences between the European Union and the Member States as laid down in the Treaty on the Functioning of the European Union. This concerns in particular the articles on Services of General Interest from which it remains exclusively for the Member States to define the fundamental principles of their social security, vocational training and health systems and to shape the framework conditions for the management, financing, organization and delivery of the services supplied within those systems.

Subsector 4 - Diagnostics sector	The specific diagnostics sector is derived from the medical devices sector. It encompasses all the specific activities carried by a laboratory as the biological analysis, molecular diagnostics or in vitro diagnostic tests.
Subsector 5 - eHealth sector	Used over time to designate ICT applications in the health domain, eHealth is a recent term with various different definitions. From the European Commission, eHealth is "the ICT tools and services for health. It covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals". So, the eHealth sector includes many dimensions, as telemedicine, electronic health records, mHealth as well as virtual healthcare teams, consumer health informatics, healthcare information systems, etc.

Following these subsectors categorizing the biomedical technologies sector, the selected technical committees were classified. Table 8 below lists the 42 selected standardization technical committees related to the biomedical technologies according to the 5 subsectors. In addition, in order to have access to more detail information, a detailed ID-card of each technical committee is presented in Chapter 6.

Table 8: Technical committees selected according to biomedical technologies subsectors

SUBSECTOR	ORIGINE*	TECHNICAL COMMITTEE (TC)	ID-CARD Ref. Page
MEDICAL DEVICES	EU	CEN/TC 205 - Non-active medical devices	p 59
	EU	CEN/CLC/JWG/AIMD CEN/CENELEC - Joint Working Group on Active Implantable Medical Devices	p 61
	INT	ISO/TC 76 - Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use	p 63
	INT	ISO/TC 84 - Devices for administration of medicinal products and intravascular catheters	p 65
	INT	ISO/TC 106 - Dentistry	p 67
	INT	ISO /TC 150 - Implants for surgery	p 70
	INT	ISO/TC 157 - Non-systemic contraceptives and STI barrier prophylactics	p 73
	INT	ISO/TC 168 - Prosthetics and orthotics	p 75
	INT	ISO/TC 170 - Surgical instruments	p 77
	INT	ISO/TC 210 - Quality management and corresponding general aspects for medical devices	p 79

SUBSECTOR	ORIGINE*	TECHNICAL COMMITTEE (TC)	ID-CARD Ref. Page
MEDICAL EQUIPMENT	EU	CEN/TC 102 - Sterilizers for medical purposes	p 82
	EU	CEN/TC 215 - Respiratory and anaesthetic equipment	p 84
	EU	CEN/TC 239 - Rescue systems	p 86
	EU	CEN/TC 332 - Laboratory equipment	p 88
	EU	CENELEC/TC 62 - Electrical equipment in medical practice	p 90
	INT	ISO/TC 48 - Laboratory equipment	p 92
	INT	ISO/TC 121 - Anaesthetic and respiratory equipment	p 94
	INT	ISO/TC 172 - Optics and photonics	p 97
	INT	ISO/TC 173 - Assistive products for persons with disability	p 99
	INT	ISO/TC 198 - Sterilization of health care products	p 101
	INT	IEC/TC 62 -Electrical equipment in medical practice	p 103
MEDICAL SERVICES	EU	CEN/TC 362 - Project Committee - Healthcare services - Quality management systems	p 106
	EU	CEN/TC 394 - Project Committee - Services of chiropractors	p 107
	EU	CEN/TC 403 - Project Committee - Aesthetic surgery services	p 108
	EU	CEN/TC 414 -Project Committee - Services of osteopaths	p 109
	EU	CEN/WS 068 - CEN Workshop - Health care services: Basic quality criteria for health checks	p 110
DIAGNOSTICS	EU	CEN/TC 140 - In vitro diagnostic medical devices	p 112
	EU	CEN/TC 216 - Chemical disinfectants and antiseptics	p 114
	EU	CEN/TC 347 - Methods for analysis of allergens	p 117
	EU	CEN/TC 367 - Breath-alcohol testers	p 119
	EU	CENELEC/BTTF 116-2 Alcohol interlocks	p 120
	EU	CEN/WS 055 - Guidance Document for CWA 15793:2008 Laboratory Biorisk Management Standard	p 122
	INT	ISO/TC 194 - Biological evaluation of medical devices	p 124
	INT	ISO/TC 209 - Cleanrooms and associated controlled environments	p 126
	INT	ISO/TC 212 - Clinical laboratory testing and in vitro diagnostic test systems	p 128
EHEALTH	EU	CEN/TC 251 - Health informatics	p 131
	EU	ETSI Project EP eHealth	p 134
	EU	CEN/CENELEC/ETSI Project - eHealth-INTEROP	p 135
	INT	ISO/TC 215 - Health informatics	p 137
	INT	ITU/ITU-T Study Group 16 - e-health and standardization	p 139
	INT	DICOM - Digital imaging and communication in medicine	p 141
	INT	HL7 - Health Level Seven International	p 142

** EU: European origin and INT: International origin*

In summary, the 42 selected technical committees, potentially interesting for the biomedical technologies sector, are distributed as noted in Table 9 below.

Table 9: Distribution of the selected technical committees in the biomedical technologies sector

Subsector	European TC	International TC	Total
Subsector 1 – Medical devices	2	8	**10**
Subsector 2 – Medical equipment	5	6	**11**
Subsector 3 – Medical services	5	0	**5**
Subsector 4 - Diagnostics	6	3	**9**
Subsector 5 - eHealth	3	4	**7**
Total	**21**	**21**	**42**

5.2. INTERESTS FOR NATIONAL STAKEHOLDERS

If the first step was to select potentially interesting technical committees in the biomedical technologies sector and to categorize them into subsectors, the next step proposes a description of the national market and links between a specific stakeholder category and the subsectors of the biomedical technologies through possible interests. These links suggests potential participation to standardization works according to a given subsector.

Potential interests for participating in standardization works for the national stakeholders of the biomedical technologies sector could be the following (as already defined in section 4.3):

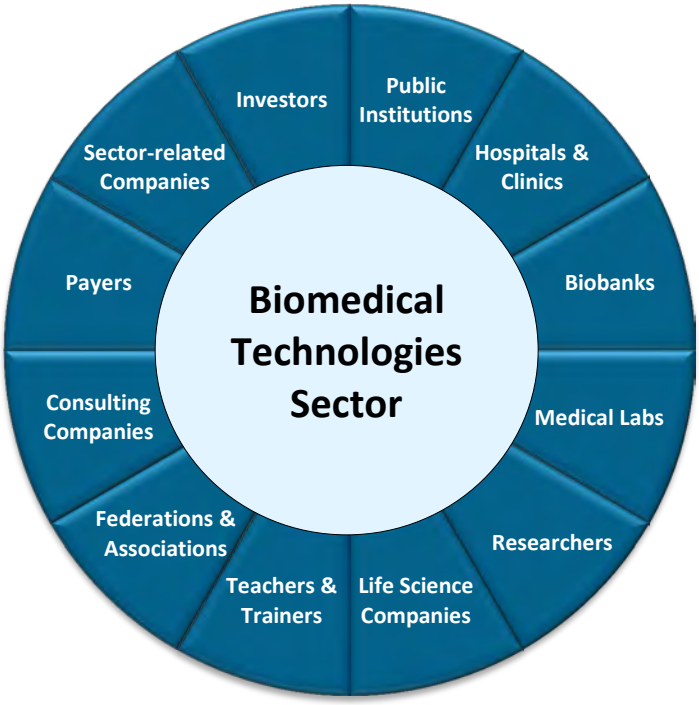
◆ **Information**	Stakeholders could have an interest in learning about standards developments.
■ **Performance**	Stakeholders could have an interest in increasing the performance of their organizations (networking/benchmarking).
❖ **Services**	Stakeholders could have an interest in developing new services.
☐ **Projects**	Stakeholders could have an interest in following or participating in research projects.
✪ **Training**	Stakeholders could have an interest in updating or developing training sessions.
$ Investments	Stakeholders could have an interest in investing in a new technology or concept.

5.2.1. DESCRIPTION OF THE NATIONAL MARKET

The national panorama of the stakeholders of the biomedical technologies sector gives a vision of the situation based on the experience and expertise of ILNAS. It reflects the situation at a certain moment from a certain point of view and is not intended to be exhaustive. Possible links and interests could have not been identified and corrections can be integrated in order to update the related matrix.

National stakeholders of the biomedical technologies sector have been reviewed by using several sources of information. Figure 5 presents a summary of the different groups of stakeholders identified during the review who are acting in this specific sector in Luxembourg.

Figure 5: Illustration of the categories of national stakeholders of the biomedical technologies sector



Each category of stakeholders is described in detail in the following paragraphs of the report.

5.2.2. PUBLIC INSTITUTIONS

a) Presentation

This category of stakeholders encompasses the public institutions in Luxembourg that take part in the development and implementation of the political actions in the national biomedical technologies sector. Among other, it contains the Ministry of Health, the Ministry of the Economy and Foreign Trade, the Ministry for Higher Education and Research and the Ministry of Social Security.

On July 29th, 2009, the Governmental Programme 2009-2014 was presented to the *Chambre des Députés*. Regarding the health sector, the Ministry of Health committed to pursuing efforts to guarantee a health system of quality. Not only focused on curative medicine, the future healthcare system would put patients at the center of the Ministry of Health's concerns and missions.
Therefore, the Ministry of Health is responsible for the implementation of the National Health Program in Luxembourg presented in 2009 during the national conference on health: "*Vers un Plan national Santé*". One of the main aims of this national program is to mobilize all the stakeholders of the healthcare sector to create efficient networks and partnerships in order to improve the health of the people of the Grand-Duchy of Luxembourg.

In the framework of this program, the Ministry of Health pursues the implementation of the *Plan d'action eSanté du Luxembourg*. Following its creation in 1995, the Healthnet network has been formalized through the constitution of the GIE Healthnet. In 2011, this GIE has got new missions and was renamed "*GIE eSanté - Agence nationale des informations partagées dans le domaine de la santé*". Its executive members are the main stakeholders directly concerned as healthcare providers, patient associations and public institutions. It is especially in charge of the implementation of the *eSanté* platform and services, the definition and promotion of interoperability guidelines. To support these activities, collaboration with HL7 Luxembourg is under discussion. Indeed, HL7 Luxembourg is an association dedicated to standardization in health informatics. Created in 2010, it is in charge of the coordination of the Luxembourg HL7 users. It also maintains contact with HL7 groups in other countries as well as scientific organizations and other actors in the area of healthcare informatics and works on the implementation of eHealth standards to answer local needs.

Under the Ministry of Health, the Health Direction, as the regulatory authority, is in charge of the elaboration and application of the health politics. Its main missions are:

- to study issues regarding public health,
- to advice the public authorities of health questions,
- to ensure compliance with legal provisions and regulations,
- to ensure the control of the sanitary situation in the country,
- to take emergency measures in terms of health protection if required,
- to collaborate at the national and international level the elaboration and implementation of the health politic.

The Ministry of the Economy and Foreign Trade in collaboration with other national ministries is in charge of the implementation of policies relating to R&D and innovation. The Ministry of the Economy and Foreign Trade ensures the implementation of a policy of economic competitiveness in Luxembourg. A specific department is dedicated to biomedical technologies: Department of Life Sciences and Technologies.
The Ministry for Higher Education and Research is largely involved in the national action plan on health technologies that initiated a partnership with 3 American research institutes to create in Luxembourg a pool of expertise in molecular diagnostics.

By supporting researchers in building up scientific quality and excellence, improving the national research environment and institutional framework, and promoting scientific culture, the National Research Fund (FNR) also supports the development of a pool of expertise within the biomedical technologies sector in Luxembourg.

A key element of the National R&D and Innovation Policy, the Luxembourg Cluster Initiative, was launched in 2002 by the Luxembourg Government to promote and support networking initiatives between the private and the public sectors. Focus was given on several key technologies that have been identified as being important to the future economic development of Luxembourg, such as healthcare and biotechnologies. The Luxembourg BioHealth Cluster is a network that brings together the major public and private stakeholders active in health sciences & technologies in Luxembourg to reinforce partnerships and collaborations to achieve innovative projects. Activities and support services of the cluster are managed by Luxinnovation GIE, the National Agency for Innovation and Research.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as a national delegate.

c) Interests to participate in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Public Institutions	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services					X
Projects					X
Training					
Investments	X	X	X	X	X

- Public institutions should be interested in following all the subsectors for information purposes. Maintaining a good level of information on all the subsectors characterizing the biomedical technologies sector should be of interest for the public institutions. For example, as a regulatory authority, the health direction should follow the standards developments and should be kept regularly informed.
- Public institutions should also have an interest in developing and acquiring new competencies and, thus, in increasing their performance, especially in areas directly supported by the National Health Program. This is the case for eHealth and also for the diagnostics subsector.
- Interest in projects, training and services are weak regarding the public institutions, as they are not directly concerned by these issues during their official activities. However, because of their particularities, some initiatives as the *GIE eSanté* could have an interest for the standardization activities of the eHealth subsector in terms of services and projects.
- Public institutions should be interested in following all the subsectors in terms of investments, especially in the domain of eHealth where the development of electronic medical records has a clear political orientation.

5.2.3. HOSPITALS & CLINICS

a) Presentation

The panorama of the hospitals and clinics located in Luxembourg encompasses among others the following institutions[23]:
Regional Hospital Centers with:

- *Centre Hospitalier de Luxembourg – CHL*
- *Centre Hospitalier du Kirchberg – CHK*
- *Centre Hospitalier Emile Mayrich – CHEM*
- *Centre Hospitalier du Nord – CHN*

Other institutions with:

- *ZithaKlinic*
- *Clinique Sainte Marie*
- *Haerzfondatioun*
- *Centre François Baclesse*
- *Rehazenter*
- *Centre Hospitalier Neuro-Psychiatrie*
- *Hôpital Intercommunal Steinfort*

The "*Plan Hospitalier National*" was published in the memorial of March 13th, 2009. The main objective of this national plan is to provide a legal framework to the future developments of the healthcare structures. In recent years, the Government of Luxembourg supported the merger of different hospitals such as the *Centre Hospitalier de Luxembourg* and the *Clinique d'Eich*, or for the creation of the *Centre Hospitalier Emile Mayrisch*.

The "*Fédération des Hôpitaux Luxembourgeois*" (FHL, formerly EHL) represents the common interests of hospitals and clinics in Luxembourg and support all forms of progress within the hospital sector, especially those concerning the well-being of the patient. It groups the hospital institutions of Luxembourg including the four regional hospital centers but also national centers in radiotherapy, cardiac surgery and interventional cardiology or in rehabilitation and specialist institutions in gynecology, obstetrics and psychiatry.

Giving more details on the 4 regional hospital centers, the *Centre Hospitalier de Luxembourg* (CHL) is a public institution under the supervision of the Ministry of Health. With more than 2 000 persons working in more than 50 different types of work, the CHL is ranked as the 11th-largest employer in Luxembourg. Opened in 1976, it covers a large range of activities in diagnosis, care, treatment, hospitalization, research and teaching. It encompasses these activities in 4 different locations: *Maternité Grande-Duchesse Charlotte, Clinique Pédiatrique, Hôpital Municipal* and since 2003, *Clinique d'Eich*.
The *Centre Hospitalier du Kirchberg* (CHK) opened in 2003 and is a general hospital that contains different services, such as a surgery department, a medicine service, and also the departments of psychiatry, pediatrics and maternity. Various specialized services and equipment are provided in addition to these basic services and contribute to achieve a modern and multidisciplinary hospital center with medical laboratory equipment or a digitized radiology and medical imaging.
Centre Hospitalier Emile Mayrisch (CHEM) results from the merger of the Esch-sur-Alzette hospital with the Dudelange hospital and the Princess Marie-Astrid hospital in Niederkorn. The CHEM exploits

[23] *http://www.sante.public.lu/fr/systeme-sante/organisation/hopitaux/index.html*

different health services on these three sites. It is considered one of the most important employers of southern Luxembourg with more 1 800 employees and 250 doctors.
Centre Hospitalier du Nord (CHN), created in 2009, encompasses 2 different sites, one in Ettelbruck and one in Wiltz. The CHN employs more than 1 000 employees with 121 doctors.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Hospitals & Clinics	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services			X	X	X
Projects				X	X
Training					
Investments					X

- Because of their organization, functioning and activities, Hospitals & Clinics should be interested in following all the subsectors for information purposes and regarding their performance. Indeed, these institutions use medical devices every day, they regularly buy medical equipment, they provide medical services to patients, they provide diagnoses, and they open their activities to eHealth technologies.
- Hospitals & Clinics should have in interest in following the subsector dedicated to medical services in order to improve their services. Indeed, the CEN/TC 362 on healthcare services could be of interest for improving the quality of service.
- Because of the political developments and strategy, it could be of interest for Hospitals & Clinics to pay attention to the standardization work in terms of projects especially in the diagnostics and eHealth subsectors. It could generate opportunities in term of participation and collaboration in research projects.
- The healthcare structures are not directly active in terms of training and thus should demonstrate weak interest for training purposes.
- Interest should be shown by Hospitals & Clinics, especially in eHealth. The political strategy promoting, for example, electronic medical records and personal health records should push the investments of the Hospitals & Clinics in this domain. Then, following standardization activities in this subsector could be of high interest for these institutions in terms of investment.

5.2.4. BIOBANKS

a) Presentation

Created in February 2010, the Integrated BioBank of Luxembourg (IBBL) is an independent, not-for-profit biobanking and biotechnology foundation. It was founded by Luxembourg's leading public research and academic centers in partnership with the Translational Genomics Research Institute (TGen), USA. It is designed to be an international center of excellence for biobanking, a leader in biospecimen research and a partner in the introduction of personalized medical care in Luxembourg.

In the last two years, IBBL has built an integrated infrastructure to collect, store and process biospecimens and associated data, which are made available to research organizations investigating human diseases under the strict observation of ethical standards. IBBL also aids researchers in analysis and provides technologies and biospecimen research to support a successful biomedical research in Luxembourg and beyond.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Biobanks	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance		X	X	X	
Services			X	X	
Projects				X	X
Training					
Investments				X	X

- Biobanks should have an interest in information on all the subsectors related to the biomedical technologies sector. Every day they use medical devices, buy biomedical equipment, and are in constant and close interaction with medical services for biospecimen collection. They collect biospecimens, which are selected and annotated with clinical biology and clinical pathology diagnostic data. They develop their activities by integrating eHealth innovations as required by the national health strategy developed in Luxembourg. In the long term biobanks can be seen as part of the health system, as all sample collection and annotations for samples, with the exception of specialized laboratory analytical results, will come from the eHealth system. Diagnoses, treatments, outcomes in addition to the clinical data mentioned above, are directly of value to the researcher using the samples.
- Biobanks should be interested in following the subsectors of medical equipment, medical services and diagnosis for performance purposes in order to adapt their procedures to technological innovations and to ensure the most relevant biospecimen annotation. It could

be an opportunity for them through participation in standardization activities to improve or develop competencies through networking with other experts, benchmarking developments, and learning of the views of other professionals of the sector. It is also very important that biobanks explain their needs to the professionals from medical sectors in order to ensure the highest biospecimen quality.

- In the diagnostics and medical services subsectors, biobanks could be interested in following the standardization work in order, for example, to improve the quality of the services provided by ensuring biospecimens are fit for purpose. In addition, it could be an opportunity for them to develop new services based, for example, on the move towards the personalized medicine.
- Biobanks should also be interested in following the diagnostics sector for project purposes. Moreover, biobanks, as a newly recognized professional sector, needs development of specific standards in the perimeter of their activities, but also need to update technical committees so that existing standards in areas of activities using biospecimens are updated in a coherent and coordinated manner.
- However, according to their activities, interest in training is low and does not justify a specific interest in following related standards technical committees for this purpose.
- Biobanks should be interested in following the diagnostics and eHealth subsectors in terms of investment. Indeed, in the coming years investments required in these domains could be largely influenced by new technologies.

5.2.5. MEDICAL LABORATORIES

a) Presentation

Different medical analysis laboratories exist in Luxembourg, including among others:

- *Laboratoire National de la Santé* (LNS),
- *Laboratoire Luxembourgeois d'Analyses Médicales* (LLAM) with *Laboratoires Ketterthill*,
- *Laboratoires Réunis*,
- *Laboratoire d'analyses médicales les Forges du Sud*.

In line with the law of the November 21st, 1980, the *Laboratoire National de la Santé* (LNS) has to fulfill several public health missions such as the study of the problems of hygiene and epidemiology, and it actively participates in the definition of the national health strategy. In addition, it is in charge of the medicine control and conducts toxicological analyses. It also carries on research in specific health domains. The laboratory is located in two different locations and employs around 185 persons. Finally, based on the law of the August 7th, 2012, the administrative status of the LNS is going to evolve in January 2013 and would become a public establishment.

Laboratoire Luxembourgeois d'Analyses Médicales (LLAM) includes the *Laboratoires Ketterthill.* The *Laboratoires Ketterthill* is considered the largest independent medical laboratory in Luxembourg. Created in 1946, around 180 people are employed by LLAM through 50 blood collection centers located throughout country. It carries also some specialized activities as with the *Laboratoire Luxembourgeois d'Immunopathologie* (LIPP). Part of the LLAM, it is considered as a reference laboratory in Europe for the characterization of autoantibodies and specializes in the study of autoimmune diseases. It analyses samples to detect the presence of autoantibodies linked to specific diseases, increasing the reliability of the diagnosis and the patients' ability to take advantage of new immunotherapies.

Laboratoires Réunis is the second-largest independent medical laboratory in Luxembourg. Founded in 1959, it currently employs 160 people through 33 blood collection centers across the country. *Laboratoires Réunis* uses molecular biomarkers in the field of infectious diseases and personalized medicine.

Laboratoire d'analyses médicales les Forges du Sud has existed for 30 years and specializes in analyzing clinical samples. With 35 employees, it possesses 14 collection centers.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), 3 persons are currently registered:

Medical laboratories	Person	Level	TC	Designation
Laboratoires Réunis	Mrs. Marie-Estelle LARCHER	International	ISO/TC 212	Clinical laboratory testing and in vitro diagnostic test systems
Laboratoire Ketterthill	Mrs. Marie-Laure FRIANT			
ILNAS/OLAS	Mr. Dominique FERRAND			

c) Interests to participate in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Medical Laboratories	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance		X	X	X	
Services			X	X	X
Projects					X
Training					
Investments				X	X

- Because of their activities, medical laboratories should have an interest in terms of information in all the subsectors related to the biomedical technologies sector. Every day they use medical devices, regularly buy medical equipment, provide medical services to patients through the realization of diagnosis, and develop their activities by integrating eHealth innovations as required by the national health strategy developed in Luxembourg.
- Medical laboratories should be interested in following the subsectors of medical equipment, medical services, and diagnosis for performance purposes. It could be a chance for them through participation in standardization activities to improve or develop competencies through networking with other experts, about benchmarking developments, and on the views of other professionals of the sector.
- In the diagnostics, in medical services or in eHealth subsectors, laboratories could be interested in following the standardization work in order, for example, to improve the quality of the diagnostics services provided. In addition, it could be an opportunity for them to develop new services based, for example, on personalized medicine issues.
- Medical laboratories should also be interested in following the eHealth sector for projects purposes. Indeed, as healthcare stakeholders, they would be fully involved in the implementation of the eSanté national plan developing and promoting eHealth applications.
- According to their activities, interest in the training of medical laboratories is low and does not justify a specific interest in following related standards technical committees for this purpose.
- Medical laboratories should be interested in following the diagnostics and eHealth subsectors in terms of investment. Indeed, in the coming years investments should be required in these domains that are largely influenced by new technologies.

5.2.6. RESEARCHERS

a) Presentation

This category describes the public research institutions in Luxembourg composed of, among other entities:

- The Public Research Centres (CRPs) such as the CRP Santé, CRP Henri Tudor,
- The University of Luxembourg with the Luxembourg Centre for Systems Biomedicine (LCSB).

The Public Research Centre for Health (*CRP-Santé*) is a public institution under the responsibility of the Health Ministry from one side and of the Ministry for Higher Education and Research from the other side. Founded in 1988, it focuses on basic, pre-clinical and clinical research concerning the life sciences in Luxembourg. In line with the major European and national health challenges and strategies, *CRP-Santé's* mission is to generate knowledge on the pathogenesis, diagnosis, and treatment of diseases that have a large impact on public health and to perform epidemiological surveillance of these diseases and research on related health determinants in the population.

The Public Research Centre Henri Tudor has a specific department, SANTEC, which is dedicated to healthcare technologies. Its research activities are dedicated to the development of methods, tools, services and solutions that can be applied by healthcare professionals, patients and citizens on a daily basis. The SANTEC research team is divided into two research units:

- The Advanced Health Informatics Unit focuses on data protection and confidentiality, applied security, international standards and technical interoperability, and on knowledge management applied to healthcare, semantic interoperability;
- The Biomedical Engineering and Public Health Unit focuses on the development of new healthcare technologies and on the analysis of their consequences on patients and the healthcare system.

The University of Luxembourg is actively involved in health research, notably in the biomedical sector. Several research units, such as the one dedicated to life sciences belonging to the Faculty of Science, Technology and Communication (FSTC), is implementing research projects and scientific activities in the biomolecular sector, for example. The Luxembourg Centre for Systems Biomedicine (LCSB), which also belongs to the University of Luxembourg, analyzes the biological mechanisms and develops systems-level approaches to gain insight into the genetic molecular and cellular mechanisms of human diseases. The Luxembourg Centre for Systems Biomedicine is highly interdisciplinary and draws expertise from a variety of disciplines (Experimental Biology, Bioinformatics and Computational Biology, Genomics-Proteomics-Metabolomics; Chemical Biology…).

Fundamental research labs are also present in Luxembourg, as with the *Laboratoire de Biologie Moléculaire et Cellulaire du Cancer* (LBMCC), which is interested in molecular mechanisms implicated in the development of resistances against chemotherapeutic agents or in the development of new therapeutic approaches based on compounds of natural origin. It collaborates with different chemist companies in order to quantify specific natural compounds or assess biological effects of extracts or purified compounds regarding cell death and inflammation mechanisms.

In addition, despite the fact that potential interests can differ on some aspects, private research initiatives have been also integrated in this category of stakeholders. For example, Fast-track Diagnostics, created in 2006 and owned by *Laboratoires Réunis,* does not only focus its activities on analyzing clinical samples; it also launches highly innovative activities. The company specializes in the

identification of infectious pathogens – agents such as viruses, bacteria and other microorganisms that cause disease – and uses advanced and innovative technologies.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as a national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Researchers	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance				X	X
Services				X	X
Projects				X	X
Training					
Investments					

- Researchers should have an obvious interest in following all the subsectors in order to collect general information. Research activities, in order to be efficient, have to go with knowledge watch in order to remain as close as possible to state of the art research.
- It should be of interest for researchers to pay attention to standardization activities in diagnostics and eHealth subsectors. It could allow them to improve their performance through networking or benchmarking issues.
- The diagnostics and eHealth subsectors could also constitute an interest for them in terms of projects as, by following relevant technical committees, it could lead to collaboration or partnerships, for example.
- In line with the aspects of networking and partnership through projects, following the diagnostics and eHealth subsectors could also constitute an interest for them in terms of developing new services.
- Because of their activities, researchers should have no special interest in training or investments in all the subsectors.

5.2.7. LIFE SCIENCE COMPANIES

a) Presentation

Considered as being strategic for the national economy, the Luxembourg Government has carried on various initiatives in recent years to promote the health sciences and technologies sector. Up to now, life sciences companies present in Luxembourg are active in various sectors, as in the medical devices or in the medical equipment sector. Through this national strategy one of the main objectives is to develop and attract other life sciences companies in Luxembourg.

To gives some illustrations of life sciences companies already active in the biomedical technologies sector in Luxembourg, some of them are presented below. It has to be kept in mind that these are only examples; it does not give a full and complete picture of the current situation.

A life sciences company of interest that can be mentioned is DuPont de Neumours Luxembourg, which employs more than 1 200 people and has developed specific activities in the biomedical technologies sector. Indeed, this international company has a branch established in Luxembourg dedicated to medical packaging that offers industrial materials with high levels of confidence and assurance to medical device manufacturers.

In addition, the Luxembourg environment offers attractive opportunities for companies in the health sciences and biotechnology sector. For example, Dometic Sarl developed a specific expertise in the area of applied special refrigeration technology in order to ensure optimal quality and safety with its Medical Systems division. Located in Luxembourg, they are mandatory for a proper, legally compliant cold chain for vital and temperature-sensitive life preserving preparations.

The Luxembourg Government wants also to promote innovative companies as with Cellon. Established in 1987 in Luxembourg, this company provides products and services to the vaccine production and bioprocessing industries. It developed innovative technologies concerning 3D tissue-culture and proposes new models for pharmaco-toxicological validation of new drugs.

Complix NV, a recently founded biopharmaceutical company, is also a life sciences company of interest for Luxembourg. It focuses on the discovery and development of a novel class of biopharmaceuticals that offers significant advantages over existing protein-based therapies. With a headquarters in Belgium, it has research facilities in Luxembourg and has developed a strategic research alliance with the CRP-Santé.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), one person is currently registered in 5 different technical committees related to the biomedical technologies sector, either at a European or at an International level.

Life science companies	Person	Level	TC	Designation
DuPont de Neumours Luxembourg S.à r.l.	Mr. Thierry WAGNER	European	CEN/TC 102 (and WG4)	Sterilizers for medical purposes (Medical packaging)
		International	ISO/TC 76 (only WG 2)	Transfusion, infusion and injection equipment for medical and pharmaceutical use (Rigid container systems and related accessories for parenterals and injectables)
		International	ISO/TC 84 (only WG 11)	Devices for administration of medicinal products and intravascular (Syringes)
		International	ISO/TC 198 (only WG7)	Sterilization of health care products (Packaging)
		International	ISO/TC 210 (and WG1)	Quality management and corresponding general aspects for medical devices (Application of quality systems to medical devices)

c) Interests to participate in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Life science companies	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X	X	X	X	X
Services				X	X
Projects				X	X
Training					
Investments	X	X	X	X	X

- Life sciences companies should have interest in following all the subsectors for information and performance purposes depending on their activities. The collection of information in general, as well as the development of performance, should constitute a main issue for them. The same observation could be done in terms of investment, as life sciences companies could potentially be interested in investing in any promising sectors. Participating in standardization activities in selected technical committees could allow for the identification of these opportunities.
- According to the actual activities of the life sciences companies present in Luxembourg and to the national health strategy, it could be of interest for them to follow the diagnostics subsectors and eHealth in terms of projects and services. This could allow them to start partnerships through projects and also to improve the quality of the services already implemented or maybe to develop new services. (A remark must be made at this stage: the improvement of products is part of the performance interest in general when the service improvement has been related to the service interests.)
- Because of their core business, life sciences companies should not be directly interested in following subsectors for training purposes.

5.2.8. TEACHERS & TRAINERS

a) Presentation

Since the law of March 26th, 1992, 23 professions are recognized as health professions in Luxembourg. Thus, several national institutions and organisms exist in order to train the future medical professionals and also to maintain up-to-date knowledge through continuous vocational training.

Secondary level training is notably taught by the *Lycée Technique pour Professions de Santé* (LTPS) and also the *Lycée Technique pour Professions Éducatives et Sociales* (LTPES).
LTPS offers training to obtain the "*brevet de technicien supérieur*" to become either a medical assistant in surgery, a nurse in anesthesia and resuscitation, a nurse in pediatrics, a midwife, or nurse in psychiatrics. LTPES specializes in the education of future educators in the health and social domain.

Regarding continuing professional training, the National Institute for the Development of Continuous Vocational Training (INFPC), a state institution under the supervision of the Ministry of the National Education and Vocational Training, proposes a list of training institutes dedicated to the health sector. Among these entities, the *Association luxembourgeoise pour la Formation Médicale Continue* (ALFORMEC) is dedicated to continuing medical vocational training. The proposed trainings are practical and oriented to primary care and public health issues. In addition, the *Centre de Formation Professionnelle Continue Dr. Robert Widong*, officially created in 2002, is also an association proposing various continuous vocational training for medical professionals on several subjects. Other associations, like the *Association Luxembourgeoise des Infirmier(e)s en Anesthésie et Réanimation* (ALIAR), the *Association Nationale des Infirmiers et Infirmières Luxembourgeois* (ANIL), or OMEGA 90 Asbl also propose professional training. Finally, the Laboratoire Ketterthill proposes a continuous medical training service for healthcare professionals through regular information using newsletters, video trainings and meetings in order to exchange on good practices.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests to participate in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Teachers & Trainers	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services					
Projects					
Training	X	X	X	X	X
Investments					

- Teachers & Trainers should be interested in following all the subsectors for information and, of course, for training purposes.
- Because of their specific focus, Teachers & Trainers dedicated to the health sector and in particular to the biomedical technologies sector should have no particular interest in terms of performance, services, projects or investments in any identified subsectors. If the improvement of training programs could be generated by following standardization work, these aspects have been integrated into the training interests.

5.2.9. FEDERATIONS & ASSOCIATIONS

a) Presentation

The healthcare professional federations and associations are well represented in Luxembourg. The different healthcare professions have their own associations in order to protect their interests and promote their activities.

A major professional association is the *Association des Médecins et Médecins-Dentistes* (AMMD) that represents the medical and medical-dental professions at a decision and strategic level in order to protect the specific interests and needs of this health profession. They also realize the promotion of good medical practices through a Scientific Council.

To mention some others, there is also the *Fédération Luxembourgeoise des Laboratoires d'Analyses Médicales* (FLLAM) that supports the collaboration of the national medical laboratories, the *Syndicat des Pharmaciens Luxembourgeois asbl*, and the *Association Pharmaceutique Luxembourgeoise*, dedicated to the pharmaceutical professionals. The *Confédération des organismes prestataires d'aides et de soins* (COPAS) represents the service providers dedicated to elderly, sick and disabled people, whether at home or in institutions.

There are also some associations dedicated to specific domains of healthcare activities, such as the *Société Luxembourgeoise de Cardiologie*, created in 2004, which focuses on the cardiovascular medicine, and the *Société Luxembourgeoise d'Oncologie,* which is a professional association that gathers medical oncologists, radiotherapists and hematologists of Luxembourg in order to improve their knowledge of oncology.

Associations are also dedicated to patients or to specific diseases or health issues. This is the case of the *Patiente Vertriedung* asbl that has as its main objective patient information in terms of rights and duties. It can also be interesting to give as an example the *Association Luxembourgeoise du diabète* and the *Alzeimer Europe Association*.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Federations & Associations	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services	X	X	X	X	X
Projects					
Training					
Investments					

- Federations & Associations should be interested in following all the subsectors for information and for service purposes. For most of them, they have a clear mission of information for their members. In addition, it should also be interesting for them through the follow-up of the standardization work of specific committees to improve or extend their services according to their members.
- Because of their specific focus, Federations & Associations should have no particular interest in terms of performance, projects, training or investments in any identified subsectors.

5.2.10. CONSULTING COMPANIES

a) Presentation

This category of stakeholders groups the consulting companies that support the healthcare sector and, in particular, the biomedical technologies sector in their activities and business. It encompasses lawyers, consultants, and auditors who specialize in the healthcare sector.

Among the biggest representatives, the Big Four firms – KPMG, Ernst & Young, PwC and Deloitte – have specific branches of their activities dedicated to life sciences and healthcare.

Deloitte has an expert group dedicated to Life Sciences and Healthcare in order to support clients in addressing challenges that impact the industry in this domain. Deloitte proposes innovative solutions to help its clients to meet their needs and achieve their objectives.

Ernst & Young created a Global Life Sciences Center with a team of professionals working to provide assurance, tax, transaction and advisory services to the industry's leaders in the area of biotechnology, pharmacology and medical technology.

KPMG with its Global Healthcare Center of Excellence supports clients in the healthcare sector. Through a global network of practitioners, it provides their clients immediate access to the latest industry knowledge, skills, resources and leadership experience.

Finally, PwC has a specific department in Luxembourg dedicated to Pharmaceutical and Life Sciences. It is considered one of the largest healthcare professional services firms with a solid consulting network. In looking at the Luxembourg context, PwC took an active part in the conduct of the national project in biomedical research launched by the Government in 2008. Indeed, PwC assisted the Government during the planning phase of this international partnership. In addition, following a request from the Minister of Health, PwC carried out research on the opportunities to implement in Luxembourg an interoperability platform and a dedicated agency for eHealth services.[24] They also provide recommendations for this platform as well as for related preliminary decisions to be made, such as the setup of a dedicated agency.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

[24] *http://www.pwc.lu/en/life-sciences/ehsps.jhtml*

Consulting companies	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services	X	X	X	X	X
Projects					
Training					
Investments					

- Consulting companies should be interested in following all the subsectors for information purposes. To be able to provide a high level of expertise in the domain of the biomedical technologies, consulting companies should stay informed in all the defined subsectors.
- In addition, they could have an interest in terms of Services in following specific standardization technical committees. This could help them to improve the quality of their services and also to develop new services for the sector.
- Because of their specific focus, consulting companies should have no other direct interest in any other identified subsectors.

5.2.11. PAYERS

a) Presentation

These stakeholders gather public and private institutions in charge of financing and supporting the costs of the healthcare and medical care.

It encompasses the *Centre Commun de la Sécurité Sociale* (CCSS), a public institution under the supervision of the Ministry of the Social Security. Its main missions are to organize the computerization and affiliation of persons covered by national health insurance.

From the public perspective, there is also the official entity in Luxembourg in charge of the reimbursement of medical costs, the *Caisse Nationale de Santé (CNS)*, the Luxembourg National Health Fund. This entity resulted from the merger of several institutions and was created under the law of the May 13th, 2008 related to the introduction of the *Statut Unique.* The CNS is the common contact point for all insured persons. In addition, it also fulfills the mission of information dedicated to patients and healthcare professionals regarding health and care insurance.

In parallel, there are three other public organisms in charge of the public sector:

- *Caisse de Maladie des Fonctionnaires et Employés Publics* (CMFEP),
- *Caisse de Maladie des Fonctionnaires et Employés Communaux* (CMFEC),
- *Entraide Médicale de la société nationale des Chemins de Fer Luxembourgeois* (EMCFL).

From the private perspective, complementary health insurance contributes with the National Health Fund to the social protection of the patients. They play a complementary role in the support of medical costs. In Luxembourg, they are grouped in the *Fédération Nationale de la Mutualité Luxembourgeoise* (FNML). To mention a few, there is the *Caisse Medico Chirurgicale Mutualiste* (CMCM) and the *Mutualité Des Employeurs* (MDE).

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Payers	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services					
Projects					
Training					
Investments					

- Payers should be considered more as standards users than as concrete actors in terms of the standardization process. However, they could have some interests in following all the medical technologies subsectors for information purposes.

5.2.12. SECTOR-RELATED COMPANIES

a) Presentation

Around the biomedical technologies sector several companies gravitate and punctually develop and propose services and products dedicated to the needs of this sector. Even if the biomedical technologies sector is not their main economic activity and income source, this sector can constitute for these sector-related companies a non-negligible market share and, sometimes, could be a potential prospective market. This is often the case with ICT companies, for example, which target as a main business the information and communications technology sector with the development of software and other informatics solutions or the implementation of a datacenter. With the development of eHealth and telemedicine, the interest of these companies in the biomedical technologies sector has dramatically increased in recent years.

In this analysis, several companies have been identified as having a potential interest in the biomedical technologies sector in addition to their main activities. To give an illustration of these stakeholders, examples of sector-related companies based in Luxembourg are described in the following paragraphs. These are given as examples and do not reflect the variety found in this category.

As sector-related company of interest, it is interesting to mention, for example, ebrc, a specialist in the provision, on demand, of e-Continuity and e-Agility services in line with the business needs. It offers a range of tailored services in hosting and management of ICT infrastructure.
In addition, CTTL, established in Luxembourg in 1990, specializes in the provision of solutions and services in telecommunications, security systems and computer networks. These companies, among their clients, can rely on clients coming from the health sector looking for ICT solutions especially to implement eHealth technologies.

From the industrial side, it worth mentioning the company Ceodeux-Meditec, which belongs to the Rotarex Holding Group, founded in 1922. This company is specialized in the production of gas valves and developed a specific branch dedicated to the design and production of valves, regulators and integrated systems for medical gases use.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), 3 persons are currently registered in 4 different technical committees either at a European or at an International level:

Sector-related companies	Person	Level	TC	Designation
CEODEUX S.A.	Mr. Philippe LARDENAIS	European	CEN/TC 215	Respiratory and anesthetic equipment
		International	ISO/TC 121	Anesthetic and respiratory equipment
Carrosserie Comes & Cie	Mr. Gilles KLEIN	European	CEN/TC 332 (only WG6)	Laboratory equipment (Portable emergency shower devices)
ebrc S.A.	Mr. Michel ACKERMAN	International	ISO/TC 215	Health informatics

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Sector-related companies	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance	X				X
Services	X				X
Projects					
Training					
Investments					

- Sector-related companies should have interests in following all the subsectors for information purposes. The collection of information should constitute a general concern for them. Following standardization activities in selected technical committees could give them access to interesting information.
- They should also have an interest in developing their performance and their services especially in the subsectors of medical devices and eHealth. This observation is based on their actual activities and also on the fact that the Government of Luxembourg supports these subsectors by an active national health program. By following standards development, they could improve their performance, the quality of the services already implemented, or maybe develop new services.
- Finally, because of their core business, sector-related companies should have no direct interest by following subsectors for projects, training, or investments purposes.

5.2.13. INVESTORS

a) Presentation

Several investors located in Luxembourg regularly invest in the biomedical technologies sector. Some banks, as for example ING, FORTIS, and Pictet & Cie (Europe) S.A., propose some specific investment funds dedicated to the health sector. To mention other investment funds companies, IPConcept Fund Management S.A., European Investment Fund, Oppenheim Asset Management Services S.à r.l. and AXA Funds Management S.A. also have some products focusing on healthcare and medical investments.

Some of the investors are even more specialized in the health sector. This is the case, for example, of Vesalius Biocapital Partners, which has invested since 2007 in companies active in human health through venture capital funds. With 2 funds it focuses on 4 areas: therapeutics, medical devices, diagnostics and novel food applications. Vesalius Biocapital Partners invests in all stages of development and often in the early stages.

From the Luxembourg Government side, national initiatives have been launched in order to support the development of biomedical technologies in Luxembourg.
The Ministry of Finance and the Ministry of the Economy and Foreign Trade have recently presented the Life Science Fund,[25] which targets biomedical technologies. Within the framework of the Health National Action plan presented in 2007 by Luxembourg's Government, it has been decided to invest, through the *Société Nationale de Crédit et d'Investissement* (SNCI), in a risk capital fund specialized in the field of biomedical sciences. After a selection process, the Advent Venture Partners group in London has been selected to initiate the first fund exclusively dedicated to biomedical technologies. This dedicated fund will surely play a key role in the effort to strengthen the biomedical sector in Luxembourg, since it encourages investment to boost innovative projects.

b) Current national delegates

Based on the national register of standardization delegates (version 50 of July 3rd, 2012), no one from this category of stakeholders is currently registered as national delegate.

c) Interests in participating in the standardization process

Based on the results of the standards watch, several subsectors of the biomedical technologies sector have been identified. This part proposes to draw links between subsectors and a given category through potential interests.

Investors	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Information	X	X	X	X	X
Performance					
Services					
Projects					
Training					
Investments	X	X	X	X	X

[25] *http://www.eco.public.lu/salle_de_presse/com_presse_et_art_actu/2012/01/19_Fonds/index.html*

- Investors should be interested in following all the subsectors for information and for investments purposes. To summarize, Investors should maintain a high level of information in all the subsectors in order to be able to invest in the most promising sectors.
- Because of their specific focus, Investors should have no other direct interest in any identified subsectors.

5.3. OPPORTUNITIES FOR THE NATIONAL MARKET

The main aim of this analysis is to increase the participation of the national stakeholders in the standardization activities. Previous steps of the standards analysis have permitted the identification and selection of standardization technical committees in terms of being current, dynamic and strategic and, through a link with the different stakeholder categories involved in the biomedical technologies sector in Luxembourg, to point out potential interests for the national players to follow standardization activities. Then, thanks to the potential interests identified for each stakeholder category, opportunities for the national market dedicated to the biomedical technologies sector can be identified and recommended in this report. Indeed, based on common interests shared between different categories of stakeholders, opportunities for future developments in order to give an answer to these identified needs can be proposed.

The following matrix (Figure 6), encompassing the overall categories, provides a clear picture of all potential interests shared between the national stakeholders. This matrix intends to help in proposing opportunities for the market by identifying the common interests of the national market.

Figure 6: Global matrix

Biomedical technologies sector	Subsector 1 Medical devices	Subsector 2 Medical equipment	Subsector 3 Medical services	Subsector 4 Diagnostics	Subsector 5 eHealth
Public institutions	◆■$	◆■$	◆■$	◆■$	◆■$
Hospitals & Clinics	◆■	◆■	◆■❖	◆■□	◆■□$
Biobanks	◆	◆■	◆■❖	◆■❖□$	◆$
Medical Labs	◆	◆■	◆■❖	◆■❖$	◆❖□$
Researchers	◆	◆	◆	◆■❖□	◆■❖□
Life Science Companies	◆■$	◆■$	◆■$	◆■❖□$	◆■❖□$
Teachers & Trainers	◆○	◆○	◆○	◆○	◆○
Federations & Associations	◆❖	◆❖	◆❖	◆❖	◆❖
Consulting Companies	◆❖	◆❖	◆❖	◆❖	◆❖
Payers	◆	◆	◆	◆	◆
Sector-related Companies	◆■❖	◆	◆	◆	◆■❖
Investors	◆$	◆$	◆$	◆$	◆$

◆ **Information** ■ **Performance** ❖ **Services** □ **Projects** ○ **Training** $ **Investment**

Based on the matrix, it appears that the majority of stakeholders share some common interests covering all the subsectors biomedical technologies. For these common interests, therefore, opportunities for the market can be identified and proposed for discussion.

Of course, the opportunities that are listed below are only proposals. They are therefore submitted for comment to the national stakeholders of the biomedical technologies sector.

❖ Creating a national forum dedicated to standards developments

Based on the common interest identified for all the stakeholder categories in terms of need of information, the creation of a national platform dedicated to the biomedical technologies sector could be an interesting initiative. This "BiomedTech Standardization Forum" conducted by ILNAS could be the place for the respective stakeholders to collect, share, and exchange information and knowledge related to the biomedical technologies sector in terms of standards development.
It could be an interesting opportunity to create a group encompassing members that would like to follow in more detail information related to the standardization work realized in the biomedical technologies sector. ILNAS, helped by ANEC, would conduct this forum and when possible would transmit pertinent and useful information to the members.

This platform could share some activities with the BioHealth Cluster of Luxinnovation, a national initiative already in place to facilitate the exchange between players acting in the Health Sciences & Technologies sector.

In addition, the future deployment of the interoperability platform of the GIE eSanté would probably require assistance and support in terms of information related to standardization. The development of a national forum dedicated to standards activities in the biomedical technologies could provide material for the platform.

❖ Supporting national delegates involved in standardization

In being the Luxembourg's national standards body, one of the missions of ILNAS is to provide support to national delegates and to coordinate the activities of the different committees at the national level. These duties are of primary importance and well stated in the national standardization strategy[26] through the following objectives:

- Ensure the sector-based economic approach of the "*Organisme Luxembourgeois de Normalisation*" (pillar III),
- Provide support to technical committees and delegates in standardization (pillar V).

Thus, a result expected from standards analysis focusing on the biomedical technologies sector is to raise awareness and increase the participation of the Luxembourg stakeholders in standardization technical committees, either at a European or an international level, in this sector.

Based on the identification of needs for new standards, as for the biobanks for example, ILNAS would provide specific support to stakeholders' initiatives to engage the development of new standards.

[26] *http://www.ilnas.public.lu/fr/publications/normalisation/etudes-nationales*

Luxembourg could like this be a key player at the European and international level in the development of new standards and take the lead in innovative fields and emerging related services.

❖ Providing services in relation to standards evolutions

Services in relation to standards and their development could be proposed to the biomedical technologies sector. It could be, for example, a standards watch focusing on a specific subsector such as eHealth or a thematic search associating regulatory requirements and standardization duties.
The identification of services to be developed that potentially answer to the expectations of the national stakeholders of the sector would be realized according to the comments received after the release of this standards analysis report.

❖ Following research projects involving standardization

If the biomedical technologies sector was identified as a promising sector for the national economic market by the Minister of the Economy and Foreign Trade, this is partly because a lot of projects in this domain are initiated in Europe and around the world. The close collaboration with US research institutes through a major project initiated in June 2008 in the biomedical research is a good example.
But, as mentioned by the CENELEC [27], many EU calls for research and innovation place standardization as a key activity, deliverable, or expected outcome of future projects. In the biomedical technologies sector, compliance with health and safety requirements is of great importance. So it might be extremely worthwhile for researchers carrying out projects to participate in standardization work. It would help researchers in preparation and project activities, in the codification of the state of the art. Taking into account standards when conducting projects ensures the compliance of the project results with regulatory requirements (e.g. Medical Devices Directive), and it can also enhance the interoperability, comparability, and compatibility of the project results with what already exists.
An example to illustrate these aspects could be the SPIDIA-project[28], funded by the European Union FP7 program, which brings together a consortium of 16 leading academic institutions, international organizations, and life sciences companies. In the proposal of this project, existing in-vitro diagnostic medical device European standards were taken into account (EN591:2001 and EN 12322:1999). In addition, the project aims to tackle the standardization and improvement of pre-analytical procedures for in-vitro diagnostics.
With the support of Luxembourg standards body, national stakeholders of the biomedical technologies sector could have opportunities to be involved in these research projects.

❖ Strengthen the existing training offers for the sector

Based on the training already provided to healthcare professionals, it could be interesting to integrate modules dedicated to standardization with a direct link to the biomedical technologies. By training the trainers on standardization activities and development related to this sector, it would guarantee that the trainers, and thus the trainees, would be in line with the state of the art at the European and international level.

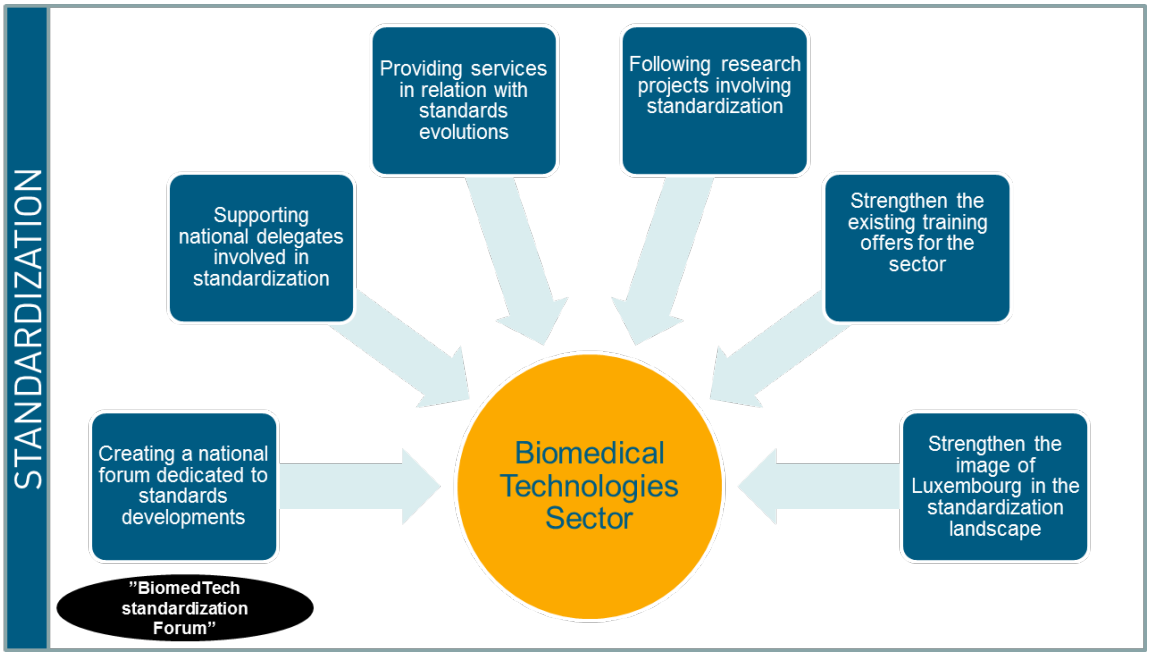
[27] *http://www.cencenelec.eu/News/Publications/Publications/LinkingResearch.pdf*
[28] *www.spidia.eu*

❖ **Strengthen the image of Luxembourg in the standardization landscape**

Through an enhancement of the participation in the standardization work and the implementation of the opportunities listed above, Luxembourg should strengthen its presence in the standardization field and significantly improve its image at the European and international levels.

To summarize, opportunities identified for the national market related to the standardization activities of the biomedical technologies sector are illustrated in Figure 7.

Figure 7: Opportunities for the national market



As long as the stakeholders of the sector wish to seize these opportunities, ILNAS, supported by ANEC, will provide an active contribution and support.

In being Luxembourg's national standards body, ILNAS offers the possibilities to national stakeholders to follow specific standardization works of technical committees, either at the European or international level.
ILNAS supports interested persons in their participation in standardization activities through appropriate information and training. Therefore, resources from ILNAS and ANEC are specifically dedicated to these aspects and are able to efficiently support and inform the future national delegates.

To reinforce this support, it is proposed to dedicate a person that would be the specific contact point for the delegates of the biomedical technologies sector. Like this, the information and support provided would stick as close as possible to the issues related to this sector.

6. SELECTED STANDARDIZATION TECHNICAL COMMITTEES IN DETAIL

As stated before, the technical committees were classified into 5 different subsectors:

- Subsector 1: Medical devices
- Subsector 2: Medical equipment
- Subsector 3: Medical services
- Subsector 4: Diagnostics sector
- Subsector 5: eHealth sector

The different ID-Cards are thus following this classification.

Note: The information contained in the ID-Cards was extracted on July 31st, 2012.

6.1. SUBSECTOR 1 – MEDICAL DEVICES

As stated by the Directorate-General for Health and Consumers (DG SANCO) of the European Commission, the role of medical devices in the healthcare sector is essential and their innovativeness significantly contributes to enhance the quality and efficacy of healthcare.

Indeed, this subsector encompasses a wide range of products from syringes to more sophisticated apparatus. Based on the definition found in EU Directive 2007/47/EC, a medical device is any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application. Medical devices are to be used for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception.

Therefore, if the definition of medical device is internationally more or less the same, this definition is relatively large. Then, in order to process to a more detailed categorization of the technical committees, this subsector was slightly reduced by extracting the medical equipment that will be considered in another dedicated subsector (subsector 2).

Hence, subsector 1, which is dedicated to medical devices, contains among other things medical instruments and implantable medical devices. The medical instrument sector encompasses the mechanical devices that make it possible to perform diagnostic and therapeutic manipulations in various fields of medicine. It groups the instruments used in the practice of medicine, e.g. a stethoscope, surgical instruments, a syringe, or a thermograph. An implantable medical device is a medical device that is partly or totally inserted into the human body or a natural orifice and is expected to stay there for a long period.
In addition, other types of devices have also been taken into account in this subsector, as are the dentistry products that are also classified in here.

For this subsector, 10 standardization technical committees were identified as interesting (2 at a European level and 8 at an international level).

6.1.1. CEN/TC 205 Non-active medical devices

General Information			
Creation Date	**1989**	**Non-active medical devices CEN/TC 205**	
Secretariat	DIN (Germany)		
Secretary	Mr. B. Bösler		
Chairperson	Mrs. M. De Cré		
Organizations in liaison	ISPO, WCO		
Subcommittees / Working groups	CEN/TC 205/WG 3 - Medical gloves CEN/TC 205/WG 14 - Surgical clothing and drapes, and medical face masks CEN/TC 205/WG - 15 Antimicrobial wound care dressings		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Directive 2007/47/EC** of the European Parliament of September 5th, 2007 amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC **Council Directive 93/42/EEC** of June 14th, 1993 on medical devices.		
Standardization Mandates	**M/252:** Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices **M/295:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/320:** Mandate to CEN concerning the development of European standards relating to medical devices (breast implants) **M/321:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (sub-categories for medical devices) **M/322:** Mandate to CEN, CENELEC and ETSI for the alignment of medical devices standards to the Radio and Telecommunications Terminal Equipment (RTTE) Directive **M/332:** Mandate to CEN/ CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of EN1970:2000 "beds for the disabled" **M/333:** Mandate to CEN concerning flammability of mattresses and bed bases for medical purposes **M/342:** Mandate to CEN/CENELEC concerning the development of European standards relating to medical devices (hyperbaric chambers for medical purposes) **M/432:** Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/433:** Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC, amending Directive 93/42/EEC relating to medical devices concerning graphical symbols for use in the labeling of medical devices containing phthalates **M/467:** Mandate to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots		

Business Plan	
Version	31/05/2006
Scope	The CEN/TC 205 was formed to prepare European standards for equipment known as "non-active medical devices". The range of equipment covered is large but generally covers simple and inexpensive devices used in all forms of medicine (e.g. gloves, catheters, thermometers, surgical clothing, etc.).
Executive summary	The CEN/TC 205 produced already a large number of EN standards, most of them harmonized in the context of the EU New Approach legislation. Working on 14 work items at the beginning, today the standardization activities concentrate on medical gloves, needles, intravascular catheters, and surgical clothing and drapes.
Work Program	
Published standards	85
Standards under development	21
Comments	
After a public consultation, "Recast of the Medical Devices Directives", held in 2008, the EU Commission is considering a revision of the legal framework for Medical Devices. This revision should improve and strengthen this framework and meet the growing expectations of European citizens. It shall lead to a fundamental revision of the existing directives in order to simplify and strengthen the current EU legal framework for medical devices.[29]	

[29] EU Commission, DG SANCO, Revision of the medical device directives, link: http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

6.1.2. CEN/CLC/JWG/AIMD CEN/CENELEC Joint Working Group on Active Implantable Medical Devices

General Information			
Creation Date	**1989**	**CEN/CENELEC Joint Working Group Active Implantable Medical Devices CEN/CLC/JWG AIMD**	
Secretariat	CCMC (Germany)		
Secretary	Dr. Klaus Neuder		
Chairperson	Dr. Matthias Neumann		
Organizations in liaison	-		
Subcommittees / Working groups	-		
Participating Members 	-	**Observing Members** 	-
Total	10	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Council Directive 90/385/EEC** of June 20th, 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.		
Standardization Mandates	**M/295**: Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/320**: Mandate to CEN concerning the development of European standards relating to medical devices (Subject: breast implants) **M/321**: Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (Subject: sub-categories for medical devices) **M/322:** Mandate to CEN, CENELEC and ETSI for the alignment of medical devices standards to the Radio and Telecommunications Terminal Equipment (RTTE) Directive **M/432**: Mandate to CEN and CENELEC within the framework of 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices		
Business Plan			
Version	-		
Scope	The main activity of this joint working group is to standardize all active implantable medical devices and their accessories.		
Executive summary	-		
Work Program			
Published standards	4		
	➢ EN 45502-2-3: Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems ➢ EN 45502-2-2: Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat		

	tachyarrhythmia (includes implantable defibrillators) ➢ EN 45502-2-1: Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) ➢ EN 45502-1: Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
Standards under development	1
	➢ prEN 45502-1:2010 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
Comments	
The Joint Working Group on Active Implantable Medical Devices works currently on the revision of EN standard 45502-1 according the changes made on the EU Directive. After that work, a revision of the EN standard 45502-2 will also be done. The countries involved in this work are Germany, Sweden, France, Italy and also USA for the liaison to ISO TC150.	

6.1.3. ISO/TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

General Information			
Creation Date	**1951**	**Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use ISO/TC 76**	
Secretariat	DIN (Germany)		
Secretary	Dr.-Ing. Vera Sattelmayer		
Chairperson	Dr. Bernd Mathieu		
Organizations in liaison	WHO		
Subcommittees / Working groups	TC 76/WG 1 - Soft containers for blood, blood components, and parenterals; Infusion, transfusion, and blood processing equipment TC 76/WG 2 - Rigid container systems and related accessories for parenterals and injectables TC 76/WG 4 - Elastomeric parts and components and related secondary packaging components TC 76/WG 5 - Blood collecting systems for diagnostic use TC 76/WG 6 - Primary packaging materials for medicinal products		
Participating Members 	Austria, Belgium, China, Denmark, France, Germany, Islamic Republic of Iran, Ireland, Italy, Japan, Luxembourg, Netherlands, Portugal, Spain, Sweden, Switzerland, USA, United Kingdom	**Observing Members** 	Argentina, Bosnia and Herzegovina, Cuba, Czech Republic, Finland, Greece, Hong Kong/China, Hungary, Iceland, India, Indonesia, Republic of Korea, Mauritius, Norway, Pakistan, Poland, Romani, Russian Federation, Saudi Arabia, Serbia, Singapore, Tunisia, Ukraine
Total	18	**Total**	23
Participation of Luxembourg	Yes	**National delegates**	Mr. Thierry WAGNER DuPont de Nemours Luxembourg S.à.r.l. (ISO/TC 76/WG 2)
European Directives	-		
Standardization Mandates	-		
Business Plan			
Version	30/09/2004		
Scope	This technical committee works on the standardization of transfusion, infusion, and injection equipment for medical and pharmaceutical use. Their standard activities cover the containers (such as infusion bottles, injection vials, ampoules, glass cylinders, cartridges, prefillable syringes, etc.), the devices (such as giving sets, blood collecting tubes, etc.), as well as pertinent primary and secondary packaging and functional components (such as elastomeric closures, caps, pipettes and accessories) for medical and pharmaceutical use.		

	Excluded from the scope, there is: - Performance requirements of metered devices and supplies intended for self-administration of medicinal products, non-prefilled syringes and needles and intravascular catheters (covered by ISO/TC 84), - Devices intended for respiratory therapy (covered by ISO/TC 121), - Dental cartridge syringe holder (covered by ISO/TC 106).
Executive summary	The objectives of this technical committee are to develop standards in the field of primary packaging materials and medical devices in order to address the requirements of users, regulatory authorities and manufacturers. The developed standards follow the essential requirements of the corresponding European Directives (e.g. Directive 93/42/EEC on medical devices), of the American Food and Drug Administration or the Japanese Ministry of Health. To achieve this issue and be in line with regulatory requirements, a close cooperation is in place with the European and the American Pharmacopoeia Commissions.
Work Program	
Published standards	60
Standards under development	5
	➢ ISO/DIS 3826-1: Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers ➢ ISO 8536-4:2010/DAmd 1 : Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed - Amendment 1 ➢ ISO 8536-12:2007/DAmd 1: Infusion equipment for medical use - Part 12: Check valves- Amendment 1 ➢ ISO/NP 11040-4: Prefilled syringes - Part 4: Glass barrels for injectables and ready-to-use prefillable syringes ➢ ISO/AWI 11040-7: Prefilled syringes - Part 7: Packaging systems for prefillable ready-to-use syringes
Comments	
The microbiological aspects and questions of biocompatibility are increasingly taken into account by ISO/TC 76. These issues require a close interaction with ISO/TC 194 "Biological evaluation of medical devices" in order to be in line with the requirements and test methods laid down in this technical committee. Close cooperation with other technical committees (e.g. ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters", ISO/TC 176/SC 2 "Quality management and quality assurance - Quality systems", ISO/TC 198 "Sterilization of health care products", and ISO/TC 210 "Quality management and corresponding general aspects for medical devices") and with the European Standardization body CEN/TC 205 "Non-active medical devices" is also in place.	

6.1.4. ISO/TC 84 Devices for administration of medicinal products and intravascular catheters

General Information			
Creation Date	**1956**	**Devices for administration of medicinal products and intravascular catheters ISO/TC 84**	
Secretariat	DS (Denmark)		
Secretary	Mrs. Helene Jackson		
Chairperson	Mr. Hal Yeager		
Organizations in liaison	EUCOMED, WHO		
Subcommittees / Working groups	TC 84/WG 3 - Syringes for insulin and pen-injectors TC 84/WG 4 - Needle-free injectors TC 84/WG 6 - Auto-injectors TC 84/WG 7 - Safety issues for needles TC 84/WG 8 - Sharps containers TC 84/WG 9 - Catheters TC 84/WG 10 - Needles TC 84/WG 11 - Syringes		
Participating Members 	Belgium, Canada, China, Denmark, Finland, France, Germany, India, Islamic Republic of Iran, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Malaysia, Netherlands, Portugal, Romania, Russian Federation, Slovakia, South Africa, Spain, Sweden, Switzerland, USA, United Kingdom, Zimbabwe	**Observing Members** 	Argentina, Australia, Austria, Colombia, Cuba, Czech Republic, Egypt, Estonia, Greece, Hong Kong/China, Hungary, Iceland, Indonesia, Mauritius, Mongolia, Norway, Pakistan, Poland, Saudi Arabia, Serbia, Seychelles, Thailand, Tunisia, Ukraine, Vietnam
Total	28	**Total**	25
Participation of Luxembourg	Yes	**National delegates**	Mr. Thierry WAGNER DuPont de Nemours Luxembourg S.à r.l. (ISO/TC 84/WG 11)
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	08/11/2004
Scope	The ISO/TC 84 standardization activities cover the performance of metered devices and supplies intended for administration of medicinal products, and of syringes, needles, and intravascular catheters. The following devices are excluded from the scope: - non-catheter devices intended for diagnostic use, - anesthetic and respiratory equipment, including lung ventilators and oxygen therapy devices (covered by ISO/TC 121),

	- cartridge systems for dental use (covered by ISO/TC 106), - specific requirements for components and devices, including prefilled syringes (covered by ISO/TC 76).
Executive summary	The main objective of the ISO/TC 84 is to establish performance requirements related to safety of the devices used for administration of medicinal products and intravascular catheters. The technical committee works on the update of existing standards and also on the development of new standards, but these new developments will be kept at a minimum and of a horizontal nature.
Work Program	
Published standards	34
Standards under development	13
	➢ ISO/NP 595-2: Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements, and tests ➢ ISO/NP 7864 : Sterile hypodermic needles for single use ➢ ISO/NP 8537: Sterile single-use syringes, with or without needle, for insulin ➢ ISO/NP 9626: Stainless steel needle tubing for the manufacture of medical devices ➢ ISO/DIS 10555-1: Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements ➢ ISO/CD 10555-2 : Sterile, single-use intravascular catheters - Part 2: Angiographic catheters ➢ ISO/DIS 10555-3: Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters ➢ ISO/DIS 10555-4 : Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters ➢ ISO/DIS 10555-5: Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters ➢ ISO/CD 10555-6: Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports ➢ ISO/FDIS 11608-3: Needle-based injection systems for medical use - Requirements and test methods - Part 3: Finished containers ➢ ISO/FDIS 11608-5: Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions ➢ ISO/FDIS 23907: Sharps injury protection - Requirements and test methods - Sharps containers
Comments	
The ISO/TC 84 works in close collaboration with other technical committees, such as ISO/TC 76 "Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use", ISO/TC 121/SC 3 "Anaesthetic and respiratory equipment - Lung ventilators and related equipment", ISO/TC 150/SC 2 "Implants for surgery - Cardiovascular implants and extracorporeal systems", ISO/TC 173/SC 2 "Assistive products for persons with disability - Classification and terminology", ISO/TC 210 "Quality management and corresponding general aspects for medical devices" and ISO/TC 215 "Health informatics".	

6.1.5. ISO/TC 106 Dentistry

General Information			
Creation Date	**1962**	**Dentistry ISO/TC 106**	
Secretariat	SCC (Canada)		
Secretary	Mrs. Sylvia Lefebvre		
Chairperson	Prof. Derek Jones		
Organizations in liaison	EC, FIDE, WCO, WHO		
Subcommittees / Working groups	TC 106/SC 1 - Filling and restorative materials TC 106/SC 2 - Prosthodontic materials TC 106/SC 3 - Terminology TC 106/SC 4 - Dental instruments TC 106/SC 6 - Dental equipment TC 106/SC 7 - Oral care products TC 106/SC 8 - Dental implants TC 106/SC 9 - Dental CAD/CAM systems TC 106/WG 10 - Biological evaluation TC 42/WG 17 - Joint TC 42/WG 3-TC 106-FDI WG : Revision of ISO 3665		
Participating Members 	Australia, Austria, Belgium, Canada, China, Finland, France, Germany, India, Islamic Republic of Iran, Ireland, Israel, Italy, Japan, Republic of Korea, Mongolia, Netherlands, Norway, Portugal, Russian Federation, Spain, Sweden, Switzerland, Thailand, USA, United Kingdom	**Observing Members** 	Argentina, Belarus, Brazil, Cuba, Czech Republic, Greece, Hong Kong/China, Hungary, Malaysia, Poland, Romania, Saudi Arabia, Serbia, Slovakia, Syrian Arab Republic, Tunisia, Turkey, Ukraine
Total	26	**Total**	18
Participation of Luxembourg	No	**National delegates**	No registered delegate
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	06/07/2005
Scope	The ISO/TC 106 standardization work is realized in the oral healthcare domain. It develops standards with which industrials should comply to ensure that their dental products that will be used in dentistry are safe and fit for their intended purpose. Amongst others, the technical committee activities include: - specification of terms and definitions, - development of performance, safety and specification requirements of dental products, - development of clinically relevant laboratory test methods.

Executive summary	The technical committee has the following objectives: - to develop international standards that are congruent with the scope of the committee and to revise or withdraw all other standards when it is required in order to maintain the quality of the existing standards and to follow the evolution of the dentistry practice, - to develop standards that make the best use of available scientific data, - to be vigilant in harmonizing standards for similar types of products, - to develop standards based upon function, utilization and safety requirements rather than on chemical and physical properties.
Work Program	
Published standards	162
Standards under development	38
	➢ ISO/NP 595-2: Reusable all-glass or metal-and-glass syringes for medical use - Part 2: Design, performance requirements and tests ➢ ISO/DIS 1797-3: Dentistry - Shanks for rotary instruments - Part 3: Shanks made of ceramics ➢ ISO/DIS 3630-2: Dentistry - Endodontic instruments - Part 2: Enlargers ➢ ISO/NP 3630-3: Dental root-canal instruments - Part 3: Condensers, pluggers and spreaders ➢ ISO/NP 4823: Dentistry - Elastomeric impression materials ➢ ISO/DIS 6873: Dentistry - Gypsum products ➢ ISO/FDIS 6876: Dentistry - Root canal sealing materials ➢ ISO 7405:2008/DAmd 1: Dentistry - Evaluation of biocompatibility of medical devices used in dentistry - Amendment 1 ➢ ISO/NP 7494-2: Dentistry - Dental units - Part 2: Water and air supply ➢ ISO/CD 9173-3: Dentistry - Extraction forceps - Part 3: Design and dimensions ➢ ISO/AWI 9680: Dentistry - Operating lights ➢ ISO/NP 9687: Dental equipment - Graphical symbols ➢ ISO/NP 9693-2: Dentistry - Compatibility testing - Part 2: Ceramic-ceramic systems ➢ ISO/FDIS 10323: Dentistry - Bore diameters for rotary instruments such as discs and wheels ➢ ISO/CD 11499: Dentistry - Single-use cartridges for local anaesthetics ➢ ISO/DIS 12836: Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy ➢ ISO/FDIS 13017: Dentistry - Magnetic attachments ➢ ISO/FDIS 13078: Dentistry - Dental furnace - Test method for temperature measurement with separate thermocouple ➢ ISO 13397-2:2005/DAmd 1: Colour coding ➢ ISO/AWI 13397-5: Dentistry - Periodontal curettes, dental scalers and excavators - Part 5: Jacquette scalers ➢ ISO/FDIS 13504: Dentistry - General requirements for instruments and related accessories used in dental implant placement and treatment ➢ ISO/FDIS 14457: Dentistry - Handpieces and motors ➢ ISO/NP 16202-1: Dentistry - Classification and codification of oral anomalies - Part 1: Structure of the classification ➢ ISO/NP 16202-2: Dentistry - Classification and codification of oral anomalies - Part 2: Developmental disturbances of teeth ➢ ISO/CD 16443: Dentistry - Terminology of oral implantology ➢ ISO/DIS 16498: Dentistry - Minimal dental implant data set for clinical use ➢ ISO/DIS 16635-1: Dentistry - Dental dam technique - Part 1: Hole punch ➢ ISO/CD 16635-2: Dentistry - Rubber dam technique - Part 2: Rubber dam clamp

	forceps ➢ ISO/AWI 16954: Dentistry - Test methods for evaluating microbiological treatment methods for dental unit procedural water ➢ ISO/CD 17304: Dentistry - Polymerisation shrinkage: Method for determination of polymerisation shrinkage of polymer-based restorative materials ➢ ISO/CD 17730: Fluoride Varnishes ➢ ISO/AWI 17937: Dentistry - Osteotomy ➢ ISO/NP TS 17988: Dentistry - Corrosion test methods for amalgam ➢ ISO/DIS 21563: Dentistry - Hydrocolloid impression materials ➢ ISO/FDIS 21672-2: Dentistry - Periodontal probes - Part 2: Designation ➢ ISO/NP 22674: Dentistry - Metallic materials for fixed and removable restorations and appliances ➢ ISO/CD 28888: Dentistry - Screening method for erosion potential of oral rinses on dental hard tissues ➢ ISO/DIS 29022: Dentistry - Adhesion - Notched-edge shear bond strength test

Comments

The ISO/TC 106 works in close cooperation with its European counterpart, the technical committee CEN/TC 55 "Dentistry". It works also in liaison with other ISO Committees (e.g. ISO/TC 42 "Photography", ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters", ISO/TC 150 "Implants for surgery", ISO/TC 194 "Biological evaluation of medical devices", ISO/TC 210 Quality management and corresponding general aspects for medical devices", ISO/TC 215 "Health informatics" or ISO/TC 217 Cosmetics).

ISO/TC 106 works also in close collaboration with the International Dental Federation in the development of clinical standards. Among these standards, it is interesting to mention for example the ISO standard 11143:2008 "Dentistry – Amalgam separators" which handles issues related to the dental mercury used in amalgam fillings and its social and environmental implications. Another interesting standard is the ISO standard 7405:2008 "Dentistry – Evaluation of biocompatibility of medical devices used in dentistry" which specifies test methods for the evaluation of biological effects.

6.1.6. ISO /TC 150 Implants for surgery

General Information			
Creation Date	**1971**	**Implants for surgery ISO/TC 150**	
Secretariat	Din (Germany)		
Secretary	Dipl.-Ing. (FH) E. Leitner		
Chairperson	Mr. John Goode		
Organizations in liaison	-		
Subcommittees / Working groups	TC 150/SC 1 - Materials TC 150/SC 2 - Cardiovascular implants and extracorporeal systems TC 150/SC 3 - Neurosurgical implants TC 150/SC 4 - Bone and joint replacements TC 150/SC 5 - Osteosynthesis and spinal devices TC 150/SC 6 - Active implants TC 150/SC 7 - Tissue-engineered medical products TC 150/WG 7 - Fundamental standards TC 150/WG 8 - Breast implants - STANDBY TC 150/WG 10 - Data on implanted and retrieved devices		
Participating Members 	Australia, Austria, Belgium, Brazil, Canada, China, France, Germany, India, Islamic Republic of Iran, Ireland, Italy, Japan, Republic of Korea, Malaysia, Netherlands, Romania, Russian Federation, Spain, Sweden, Switzerland, Turkey, USA, United Kingdom	**Observing Members** 	Argentina, Cuba, Czech Republic, Denmark, Estonia, Finland, Hong Kong/China, Hungary, Israel, Lithuania, Norway, Poland, Portugal, Saudi Arabia, Serbia, Singapore, Thailand, Tunisia, Ukraine
Total	24	**Total**	19
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	11/12/2007
Scope	The ISO/TC 150 sets standards for active and non-active medical devices that are implanted in the body either permanently or temporarily for therapeutic or diagnostic purposes. These implants are dedicated to replace, repair or stimulate defective or worn-out or damaged parts of the body. The range of products is from highly sophisticated complete systems (such as a pacemaker) to 'simple' semi-finished products (such as a bone screw) to components or materials (such as implantable stainless steel).
Executive summary	The main objective of the committee is to produce and maintain the standards for almost all types of implants used in surgery. The ISO/TC 150 expects to satisfy three needs: the safety and comfort of the patient,

	the confidence of the surgeon in the product, and the facilitation of market access. To meet these goals, the ISO/TC 150 works on the following issues: - elaboration of standards on implants for surgery and their required instrumentation, - coverage of the terminology, - definition of specifications and requirements as well as methods of tests for all types of implants, and for the materials (both basic and composite) used in their manufacture and application.
Work Program	
Published standards	133
Standards under development	34
	➢ ISO 5832-3:1996/DAmd 1 ➢ ISO/DIS 5834-4: Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 4: Oxidation index measurement method ➢ ISO/DIS 5838-1: Implants for surgery - Metallic skeletal pins and wires - Part 1: General requirements ➢ ISO/DIS 5840-3: Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by minimally invasive techniques ➢ ISO/NP 5841-2: Implants for surgery - Cardiac pacemakers - Part 2: Reporting of clinical performance of populations of pulse generators or leads ➢ ISO/CD 5841-3: Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors (IS-1) for implantable pacemakers ➢ ISO/DIS 7206-6.3: Implants for surgery - Partial and total hip joint prostheses - Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components ➢ ISO 8637:2010/DAmd 1: Revision to Figure 2 - Main fitting dimensions of dialysis fluid inlet and outlet ports ➢ ISO/CD 8828: Implants for surgery - Guidance on care and handling of orthopaedic implants ➢ ISO/AWI 11491: Implants for surgery - Test method for impact resistance of ceramic femoral head for partial and total hip prostheses ➢ ISO/AWI 12417: Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products ➢ ISO/CD 12891-2: Retrieval and analysis of surgical implants - Part 2: Analysis of retrieved metallic surgical implants ➢ ISO/CD 12891-3: Retrieval and analysis of surgical implants - Part 3: Analysis of retrieved polymeric surgical implants ➢ ISO/CD 12891-4: Retrieval and analysis of surgical implants - Part 4: Analysis of retrieved ceramic surgical implants ➢ ISO/CD 13175-1: Implants for surgery - Calcium phosphates - Part 1: Hydroxyapatite powders ➢ ISO/FDIS 13175-3: Implants for surgery - Calcium phosphates - Part 3: Hydroxyapatite and beta-tricalcium phosphate bone substitutes ➢ ISO/DIS 13179-1: Implants for surgery - Plasma sprayed coatings of unalloyed titanium - Part 1: General requirements ➢ ISO/CD 14243-3: Implants for surgery - Wear of total knee-joint prostheses - Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test ➢ ISO/CD 14243-4: Implants for surgery - Wear of total knee prostheses - Part 4: Wear of the patella-femoral joint - Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test ➢ ISO/FDIS 14630: Non-active surgical implants - General requirements

	➢ ISO/CD 14708-1: Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking, and for information to be provided by the manufacturer ➢ ISO/FDIS 14708-2: Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers ➢ ISO/NP 14708-3: Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators ➢ ISO/NP 14708-4: Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps ➢ ISO/DIS 14708-7: Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear implant systems ➢ ISO/DIS 15309: Implants for surgery - Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices ➢ ISO/DIS 16087: Implants for surgery - Roentgen stereophotogrammetry for assessment of micromotion of orthopaedic implants ➢ ISO/CD 16376: Implants for surgery - Evaluation method of endurance performance of metallic artificial hip stem using numerical simulation with finite element analysis ➢ ISO/NP 16379: Tissue-engineered medical products - Evaluation of anisotropic structure of articular cartilage using DT (Diffusion Tensor)-MR Imaging ➢ ISO/AWI TS 17137: Cardiovascular absorbable implants ➢ ISO 21536:2007/DAmd 1 ➢ ISO/FDIS 23317: Implants for surgery - In vitro evaluation for apatite-forming ability of implant materials ➢ ISO/FDIS 25539-2: Cardiovascular implants - Endovascular devices - Part 2: Vascular stents ➢ ISO 27186:2010/AWI Amd 1IEC/DTR 62653: Guidelines for the safe use of medical products in dialysis treatment
Comments	
The ISO/TC 150 works in relationship with the European standards committee CEN/TC 285 "Non-active surgical implants". Others liaisons with ISO/TC are also maintained (e.g. TC 61, TC 106, TC 168, TC 170, TC 194, TC 198, TC 201, TC 210 or TC 215) and also with the IEC/TC 62 "Electrical equipment in medical practice".	

6.1.7. ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics

General Information			
Creation Date	**1974**	**Non-systemic contraceptives and STI barrier prophylactics ISO/TC 157**	
Secretariat	DSM (Malaysia)		
Secretary	Mrs. Roslina Harun		
Chairperson	Dr. Eng Long Ong		
Organizations in liaison	CI, DFID, EC, IPPF, PATH, UNFPA, WHO		
Subcommittees / Working groups	TC 157/TG 1 - Statistical task group TC 157/CAG - Chairman Advisory Group TC 157/WG 3 - Intrauterine devices TC 157/WG 10 - Minimum burst pressure and burst volume requirements TC 157/WG 11 - Packaging integrity TC 157/WG 12 - Determination of the amount of lubricant TC 157/WG 13 - Stability assessment TC 157/WG 14 - Guidance on the use of ISO 4074 and ISO 23409 TC 157/WG 15 - Test methods for the effect of additional lubricants on physical properties of condoms TC 157/WG 17 - Synthetic condoms TC 157/WG 18 - Female condoms TC 157/WG 19 - Methods for hole detection TC 157/WG 20 - Clinical trials TC 157/WG 21 - Determination of nitrosamines TC 157/WG 22 - Latex barrier membranes TC 157/WG 23 - Natural rubber latex condoms TC 157/WG 24 - Tubal ligation/Fallopian ring		
Participating Members 	Australia, Belgium, Brazil, Canada, China, Egypt, France, Germany, Greece, India, Japan, Republic of Korea, Malaysia, Mexico, Netherlands, Russian Federation, South Africa, Spain, Sweden, Switzerland, Thailand, USA, United Kingdom, Zimbabwe	**Observing Members** 	Argentina, Bangladesh, Botswana, Bulgaria, Cameroon, Cuba, Czech Republic, Finland, Ghana, Hungary, Islamic Republic of Iran, Ireland, Italy, Jamaica, Kenya, Mauritius, New Zealand, Norway, Poland, Portugal, Romania, Serbia, Singapore, United Republic of Tanzania, Turkey, Uganda
Total	24	**Total**	26
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	15/03/2010
Scope	The ISO/TC 157 covers all areas of non-systemic contraceptives and STI barrier prophylactics. Since its first meeting in 1975, ISO/TC 157 has expanded its scope to cover all areas of mechanical contraceptives. It varies from the single-use disposable male condom to multiple-use devices such as the intra-uterine devices.
Executive summary	The general objective of the ISO/TC 157 is to develop and refine standards for non-systemic contraceptives and STI barrier prophylactics, together with appropriate guidance documents for manufacturers, regulators and procurement agencies. Since the beginning of the HIV/AIDS epidemic in the early 1980s, ISO/TC 157 work evolved and mainly focused on condoms. To help ensure that condoms are effective both for contraceptive purposes and in the prevention of STDs, ISO/TC 157 has developed a series of specific standards.
Work Program	
Published standards	13
Standards under development	2
	➢ ISO/CD 4074: Natural rubber latex male condoms - Requirements and test methods ➢ ISO/WD 11250: Mechanical female contraceptive devices - Tubal ligation/Fallopian rings
Comments	
The published standard for male latex condoms, ISO 4074, is the most important output of the technical committee. In addition, the published standards for IUDs (ISO 7439) and rubber diaphragms (ISO 8009) can also be quoted. These standards are widely used. The ISO/TC 157 works in close collaboration with another ISO technical committee focusing on quality management and corresponding general aspects for medical devices, the ISO/TC 210. The next meeting of the technical committee should be organized in the United Kingdom during the fourth quarter of 2012.	

6.1.8. ISO/TC 168 Prosthetics and orthotics

General Information			
Creation Date	**1977**	**Prosthetics and orthotics ISO/TC 168**	
Secretariat	DIN (Germany)		
Secretary	Dipl.-Ing. Karl Wenzelewski		
Chairperson	Mr. Martin Pusch		
Organizations in liaison	ISPO, WCO		
Subcommittees / Working groups	TC 168/WG 1 - Nomenclature and classification TC 168/WG 2 - Medical aspects TC 168/WG 3 - Testing		
Participating Members 	Austria, Belgium, France, Germany, Iceland, India, Ireland , Italy, Japan, Republic of Korea, Netherlands, Romania, Spain, Sweden, USA, United Kingdom	**Observing Members** 	Belarus, China, Cuba, Czech Republic, Denmark, Finland, Hong Kong/China, Hungary, Lithuania, Norway, Poland, Saudi Arabia, Singapore, Thailand, Turkey
Total	16	**Total**	15
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	05/11/2004
Scope	The ISO/TC 168 focuses its standardization activities on the field of prosthetics and orthotics, covering such aspects as performance, safety, environmental factors, interchangeability, etc. It includes temporary and permanent procedures and devices even if priority is given to standards on prostheses (artificial limbs and auxiliary equipment).
Executive summary	The present work of the ISO/TC 168 is characterized by the elaboration of 2 different groups of standards, aiming at the establishment of: - a nomenclature and related terminology to allow all parties involved in the prosthetic/orthotic treatment of persons with physical disabilities to apply a standard terminology, and - a system of test methods for the verification of essential requirements on prosthetic/orthotic devices related to the safety of the users.

Work Program	
Published standards	21
Standards under development	3
	➢ ISO 10328:2006/DAmd 1: Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods – Amendment 1 ➢ ISO/CD 16955: Prosthetics - Quantification of physical parameters of ankle/foot devices and foot units ➢ ISO 22675:2006/DAmd 1: Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods – Amendment 1
Comments	
The ISO/TC 168/WG 3 "Testing" holds joint meetings together with WG 5 "Prostheses and orthoses" of CEN/TC 293 "Technical aids for disabled persons". In addition, members of ISO/TC 168/WG 1 and ISO/TC 168/WG 2 occasionally attend these meetings. Finally, standards developed by the ISO/TC 168 have been reinforced since the implementation of the European Directive 93/42 EEC on medical devices and the support of its application by the Harmonized European Standard EN12523 "External limb prostheses and external orthoses – Requirements and test methods".	

6.1.9. ISO/TC 170 Surgical instruments

General Information			
Creation Date	**1977**	**Surgical instruments ISO/TC 170**	
Secretariat	DIN (Germany)		
Secretary	Dipl.-Ing. Karl Wenzelewski		
Chairperson	Mr. Theodor Lutze		
Organizations in liaison	WCO, WHO		
Subcommittees / Working groups	-		
Participating Members 	Belgium, China, Germany, India, Republic of Korea, Russian Federation, United Kingdom	**Observing Members** 	Austria, Cuba, Czech Republic, Egypt, Estonia, Finland, France, Hong Kong/China, Hungary, Iceland, Italy, Mongolia, Netherlands, Romania, Saudi Arabia, Spain, Sweden, Switzerland, Thailand, Tunisia, Turkey, USA, Ukraine
Total	7	**Total**	23
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	05/11/2004
Scope	The ISO/TC 170 focuses its standardization activities in the field of surgical instruments such as forceps, scissors, scalpels and retractors. This technical committee is in charge of the development of test methods, specifications, and performance standards for these devices. Its standardization work excludes specific instruments that are dealt with in ISO/TC 106 "Dentistry" and ISO/TC 150 "Implants for surgery".
Executive summary	The ISO/TC 170 works on standards on surgical instruments, covering terminology, specifications and requirements as well as methods of tests for all types of instruments. The developed standards try to take into account: - the safety and comfort of the patient, - the confidence of the surgeon/practitioner in the product, - the facilitation of global trade and market access.

Work Program	
Published standards	6
	➢ ISO 7151:1988 : Surgical instruments - Non-cutting, articulated instruments - General requirements and test methods ➢ ISO 7153-1:1991 : Surgical instruments - Metallic materials - Part 1: Stainless steel ➢ ISO 7153-1:1991/Amd 1:1999 : Surgical instruments - Metallic materials - Part 1: Stainless steel – Amendment 1 ➢ ISO 7740:1985 : Instruments for surgery - Scalpels with detachable blades - Fitting dimensions ➢ ISO 7741:1986 : Instruments for surgery - Scissors and shears - General requirements and test methods ➢ ISO 13402:1995 : Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure
Standards under development	0
Comments	
The ISO/TC 170 works in close collaboration with the ISO/TC 150 "Implants for surgery", as many of the experts, especially ones coming from the manufacturing side, are involved in both committees. It collaborates also with the ISO/TC 106 "Dentistry" and ISO/TC 210 "Quality management and corresponding general aspects for medical devices".	

6.1.10. ISO/TC 210 Quality management and corresponding general aspects for medical devices

General Information			
Creation Date	**1994**	**Quality management and corresponding general aspects for medical devices ISO/TC 210**	
Secretariat	ANSI (USA)		
Secretary	Mrs. Hillary Woehrle		
Chairperson	Dr. Eamonn V. Hoxey		
Organizations in liaison	AHWP, DITTA, EDMA, EUCOMED, EUROM, WHO		
Subcommittees / Working groups	TC 210/WG 1 - Application of quality systems to medical devices TC 210/WG 2 - General aspects stemming from the application of quality principles to medical devices TC 210/WG 3 - Symbols and nomenclature for medical devices TC 210/TF 1 - Post Market Surveillance TC 210/JWG 1 - Joint ISO/TC 210-IEC/SC 62A WG : Application of risk management to medical devices TC 210/JWG 2 - Joint ISO/TC 210-IEC/SC 62A WG : Medical device software TC 210/JWG 3 - Joint ISO/TC 210-IEC/SC 62A WG : Medical device usability TC 210/JWG 4 - Joint ISO/TC 210-IEC/SC 62D: Small bore connectors		
Participating Members 	Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, India, Islamic Republic of Iran, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Malaysia, Netherlands, Norway, Portugal, Russian Federation, South Africa, Spain, Sweden, Switzerland, Thailand, Turkey, USA, United Kingdom	**Observing Members** 	Algeria, Bosnia and Herzegovina, Chile, Cuba, Czech Republic, Estonia, Hong Kong/China, Hungary, Jamaica, Mauritius, Mongolia, Romania, Saudi Arabia, Singapore, Slovakia, Tunisia, Uganda, Uruguay
Total	32	**Total**	18
Participation of Luxembourg	Yes	**National delegates**	Mr. Thierry WAGNER DuPont de Nemours Luxembourg S.à r.l. (ISO/TC 210/WG 1)
European Directives	-		
Standardization Mandates	-		
Business Plan			
Version	18/10/2007		
Scope	The ISO/TC 210 focuses its standardization activities in the field of quality management and corresponding general aspects for medical devices. Its standardization work excludes: - generic quality management standards dealt with by ISO/TC 176; - quality management standards for pharmaceutical products;		

	- technical requirements for specific types of medical devices.
Executive summary	The ISO/TC 210 aims to promote quality management system related requirements by using international standards. The work of ISO/TC 210 is to facilitate a worldwide exchange of medical devices and knowledge that improves the economics of the medical device industry as a whole. The ISO/TC 210 standardization work concerns quality management systems for medical device manufacturers (ISO 13485 and ISO/TR 14969) and is based on ISO 9001:2000.
Work Program	
Published standards	17
Standards under development	9
	➢ ISO/CD 13485: Medical devices - Quality management systems -- Requirements for regulatory purposes ➢ ISO/NP 16142: Medical devices - Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices ➢ ISO/TS 19218-1:2011/CD Amd 1 ➢ ISO/IEC DTR 24971: Guidance on the application of ISO 14971 ➢ IEC/CD 80369-2: Small bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for breathing systems and driving gases applications ➢ IEC/CD 80369-3: Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications ➢ IEC/CD 80369-5: Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications ➢ IEC/CD 80369-6: Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications ➢ ISO/CD 80369-7: Small bore connectors for liquids and gases in healthcare applications - Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications
Comments	
The ISO/TC 210 works in close collaboration with the IEC committees as the IEC/SC 62A "Common aspects of electrical equipment used in medical practice" to develop standards that will address the risk management-system requirements for regulatory agencies and manufacturers. It also works in collaboration with IEC/TC 56 "Dependability". As a result, there are efforts to coordinate the work of ISO/TC210 and the Global Harmonization Task Force (GHTF), whose objectives include a similar goal. In close cooperation with other interested ISO technical committees, ISO/TC 210 develops standards for small-bore connectors that are components of a wide range of medical devices. The ISO committees in liaison are: JTC 1/SC 7, TC 76, TC 84, TC 106, TC 121, TC 150, TC 157, TC 168, TC 170, TC 172/SC 7, TC 173, TC 173/SC 2, TC 176, TC 176/SC 2, TC 194, TC 198, TC 209, TC 212, TC 215.	

6.2. SUBSECTOR 2 – MEDICAL EQUIPEMENT

As previously mentioned, medical equipment subsector has been extracted from the medical devices category to be individually analyzed.

As defined in the ISO standard 13485 "Medical devices - Quality management systems - Requirements for regulatory purposes", medical equipment is mainly designed to aid in the diagnosis, monitoring or treatment of medical conditions. It generally groups all medical devices that use electrical energy or other source of power to function.
This subsector contains a large range of different types of equipment, from the simplest to the most complex. This includes:

- Diagnostic equipment includes medical imaging machines, used to aid in diagnosis (e.g. ultrasound and MRI machines, PET and CT scanners, and X-ray machines),
- Therapeutic equipment such as infusion pumps and medical lasers,
- Life-support equipment used to maintain a patient's bodily function (e.g. medical ventilators, anesthetic machines, heart-lung machines, and dialysis machines),
- Medical monitors that allow medical staff to measure a patient's medical state,
- Medical laboratory equipment that automates or helps to analyze blood, urine and genes.

In addition, it is conducive to innovation and can be seen as an efficient economic key-driver with ample opportunities of growth. Indeed, according to Espicom's June 2011 report,[30] the global market for medical equipment and supplies was valued at 273.3 billion in 2011. The compound annual growth rate (CAGR) for the period 2006-2010 was 5.3%.

For this subsector, 11 standardization technical committees were identified as interesting (5 at a European level and 6 at an international level).

[30] *World Medical Market Forecasts to2016, published by Espicom on June 30th, 2011. http://www.espicom.com/prodcat2.nsf/Product_ID_Lookup/00001541?OpenDocument*

6.2.1. CEN/TC 102 Sterilizers for medical purposes

General Information			
Creation Date	**1982**	**Sterilizers for medical purposes CEN/TC 102**	
Secretariat	DIN (Germany)		
Secretary	Dipl.-Biol. A. Müller		
Chairperson	Mr. K. Hahnen		
Organizations in liaison	SBA, EDANA, AIII, EUROM VI		
Subcommittees / Working groups	CEN/TC 102/WG 1 - Terminology CEN/TC 102/WG 2 - Testing CEN/TC 102/WG 3 - Requirements CEN/TC 102/WG 4 - Packaging materials CEN/TC 102/WG 5 - Small sterilizers CEN/TC 102/WG 6 - Gas sterilizers CEN/TC 102/WG 7 - Biological and chemical indicators CEN/TC 102/WG 8 - Performance requirements and testing for washer-disinfectors		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	Yes	**National delegates**	Mr. Thierry WAGNER DuPont de Nemours Luxembourg S.à r.l. (CEN/TC 102/WG4)
European Directives	**Directive 2007/47/EC** of the European Parliament of September 5th, 2007 amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC **Council Directive 93/42/EEC** of June 14th, 1993 concerning medical devices **Council Directive 90/385/EEC** of June 20th, 1990 on active implantable medical devices		
Standardization Mandates	**M/252**: Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices **M/295**: Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/320**: Mandate to CEN concerning the development of European standards relating to medical devices (breast implants) **M/321**: Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (sub-categories for medical devices) **M/322**: Mandate to CEN, CENELEC and ETSI for the alignment of medical devices standards to the RTTE Directive **M/332**: Mandate to CEN/ CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of EN1970:2000 "beds for the disabled" **M/333**: Mandate to CEN concerning flammability of mattresses and bed bases for medical purposes **M/342**: Mandate to CEN/CENELEC concerning the development of European standards relating to medical devices (hyperbaric chambers for medical purposes)		

	M/432: Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/433**: Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC, amending Directive 93/42/EEC relating to medical devices, concerning graphical symbols for use in the labeling of medical devices containing phthalates **M/467**: Mandate to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots
Business Plan	
Version	15/06/2012
Scope	The CEN/TC 102 standardization work concerns sterilizers, washer-disinfectors, and their associated accessories. The standards developed are designed to support the needs of industry but also of competent authorities, healthcare facilities, patients and other users of sterilized medical devices.
Executive summary	The objective of this technical committee is to develop and maintain relevant, up-to-date standards on sterilizers, washer disinfectors, and associated accessories with the objective of ensuring satisfactory cleaning, disinfection, sterilization and sterile products until the point of use. Among various goals, the standards developed by the CEN/TC 102 should ensure satisfactory cleaning, disinfection and sterilization, guaranty sterilized medical devices until the point of use, and develop standardized performance test procedures and monitoring systems.
Work Program	
Published standards	33
Standards under development	11
	➢ prEN ISO 11140-6: Sterilization of health care products - Chemical indicators - Part 6: Class 2 indicators and process challenge devices for use in performance testing for small steam sterilizers (ISO/AWI 11140-6:2007) ➢ prEN 1422 rev.: Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods ➢ prEN 16442: Controlled environment storage cabinet for disinfected thermolabile endoscopes ➢ prEN ISO 16775: Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 ➢ prEN ISO 11138-6: Sterilization of health care products - Biological Indicators - Part 6: Biological indicators for hydrogen peroxide vapour sterilization processes (ISO/NP 11138-6:2008) ➢ prEN 13060 rev.: Small steam sterilizers ➢ prEN 14180 rev.: Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing ➢ prEN ISO 11140-1 rev.: Sterilization of health care products - Chemical indicators - Part 1: General requirements ➢ EN ISO 11607-1:2009/prA1: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems ➢ EN ISO 11607-2:2006/prA1: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes ➢ EN ISO 15883-1:2009/prA1: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006/DAM 1: 2012)

Comments
To achieve its objectives, the CEN/TC 102 operates in close cooperation with CEN/TC 204 “Sterilization of medical devices” and the ISO/TC 198 "Sterilization of health care products”. The CEN/TC 102 standards activities are affected by recent developments in the fields of pressure equipment and operator safety. These developments, (corresponding to standards as EN ISO 14971, EN ISO 12100, series EN 13445, EN 14222, EN 61010-1 and EN 61010-2-040) are taken into consideration during the revision of existing standards of CEN/TC 102.

6.2.2. CEN/TC 215 Respiratory and anesthetic equipment

General Information			
Creation Date	**1989**	**Respiratory and anesthetic equipment CEN/TC 215**	
Secretariat	BSI (United-Kingdom)		
Secretary	Mr. A. Patel		
Chairperson	Mr. T. Longman		
Organizations in liaison	-		
Subcommittees / Working groups	CEN/TC 215/WG 1 - Anesthetic machines, medical breathing systems, and anesthetic gas scavenging systems CEN/TC 215/WG 2 - Lung ventilators CEN/TC 215/WG 3- Medical gas supply systems CEN/TC 215/WG 4 - Tracheal tubes and other equipment		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	Yes	**National delegates**	Mr. Philippe LARDENAIS CEODEUX S.A.
European Directives	**Directive 2007/47/EC** of the European Parliament of September 5th, 2007 amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC **Council Directive 93/42/EEC** of June 14th, 1993 on medical devices		
Standardization Mandates	**M/252:** Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices **M/295:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/320:** Mandate to CEN concerning the development of European standards relating to medical devices (breast implants) **M/321:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (sub-categories for medical devices) **M/322:** Mandate to CEN, CENELEC and ETSI for the alignment of medical device standards to the Radio and Telecommunications Terminal Equipment (RTTE) Directive **M/332:** Mandate to CEN/ CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of EN1970:2000 "beds for the disabled" **M/333:** Mandate to CEN concerning flammability of mattresses and bed bases for medical purposes **M/342:** Mandate to CEN/CENELEC concerning the development of European standards relating to medical devices (hyperbaric chambers for medical purposes) **M/432:** Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/433:** Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC, amending Directive 93/42/EEC relating to medical devices concerning graphical symbols for use in the labeling of medical devices containing phthalates **M/467**: Mandate to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots		

Business Plan	
Version	30/08/2004
Scope	The CEN/TC 215 works to prepare European standards for the equipment used to administer anesthetic agents to patients; the equipment used to convey the correct anesthetic agents and medical gases to the device or the patient at controlled flow and pressure and to conduct excess and expired gases safely away from the patient and operating room staff; equipment to monitor the patient undergoing treatment; and equipment for use in respiratory therapy and care.
Executive summary	The CEN/TC 215 seeks to develop standards to support the uniform implementation of the requirements of the Directive 93/42/EEC and a common understanding of the technical requirements between Competent Authorities, Notified Bodies, manufacturers, and users. Active participants in CEN/TC 215 include clinicians, manufacturers, test house and certification body staff, and Government health ministry staff. Three types of standards are prepared by the CEN/TC 215: - those specifying performance requirements; - those specifying performance parameters to be disclosed by the manufacturers, together with appropriate test methods by which the disclosed parameters are to be measured; - more rarely, dimensional and design specifications.
Work Program	
Published standards	68
Standards under development	20
Comments	
To achieve its objectives and to follow the Vienna agreement, the CEN/TC 215 operates in close cooperation with ISO/TC 121 "Anaesthetic and respiratory equipment".	

6.2.3. CEN/TC 239 Rescue systems

General Information			
Creation Date	**1990**	**Rescue systems CEN/TC 239**	
Secretariat	DIN (Germany)		
Secretary	Mr. B. Johns		
Chairperson	Dipl.-Ing. S. Mann		
Organizations in liaison	-		
Subcommittees / Working groups	CEN/TC 239/WG 1 - Medical vehicles and their equipment - Stretchers and other patient handling equipment CEN/TC 239/WG 5 - Air, water and difficult terrain ambulances		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Directive 2007/47/EC** of the European Parliament of September 5th, 2007 amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC **Council Directive 93/42/EEC** of June 14th, 1993 on medical devices **Council Directive 90/385/EEC** of June 20th, 1990 on active implantable medical devices **Council Directive 70/156/EEC** of February 6th, 1970 on the type-approval of motor vehicles and their trailers		
Standardization Mandates	**M/252**: Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices **M/295**: Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/320**: Mandate to CEN concerning the development of European standards relating to medical devices (breast implants) **M/321**: Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (sub-categories for medical devices) **M/322:** Mandate to CEN, CENELEC and ETSI for the alignment of medical devices standards to the Radio and Telecommunications Terminal Equipment (RTTE) Directive **M/332**: Mandate to CEN/ CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of EN1970:2000 "beds for the disabled" **M/333**: Mandate to CEN concerning flammability of mattresses and bed bases for medical purposes **M/342**: Mandate to CEN/CENELEC concerning the development of European standards relating to medical devices (hyperbaric chambers for medical purposes) **M/358**: Mandate to CEN/CENELEC/ETSI concerning electromagnetic compatibility requirements for equipment covered by the R&TTE directive intended to be installed in vehicle **M/359**: Mandate to CEN/CENELEC/for equipment covered by the EMC directive intended to be installed in vehicles		

	M/432: Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/433**: Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC, amending Directive 93/42/EEC relating to medical devices concerning graphical symbols for use in the labeling of medical devices containing phthalates **M/467**: Mandate to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots
Business Plan	
Version	21/12/2005
Scope	The CEN/TC 239 is engaged in the standardization of ambulances as emergency medical vehicles and/or crafts and their associated accessories in the interests of providing safe and comfortable transport and pre-hospital treatment for patients.
Executive summary	The CEN/TC 239 seeks to develop and maintain standards on emergency medical devices and associated accessories with the objective of providing safe and comfortable transport and pre-hospital treatment for patients. As stated in the business plan, the objectives of CEN/TC 239 include developing and maintaining up-to-date standards in order to: - achieve safe and effective transport, monitoring and treatment by standardizing medical vehicles and their medical devices, - develop standardized performance test procedures, - provide requirements on operator safety, - promote uniformity and clarity in understanding by adoption of standardized terminology.
Work Program	
Published standards	10
Standards under development	3
	➢ prEN 13718-1 rev: Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances ➢ prEN 13718-2 rev: Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements of air ambulances ➢ EN 1789:2007+A1:2010/prA2: Medical vehicles and their equipment - Road ambulances
Comments	
To achieve its objectives, the CEN/TC 339 operates in close cooperation with other European and International Technical Committees in order to ensure coherency of standards work. These other Technical Committees are: CEN/TC 192 "Fire service equipment", CEN/TC 205 "Non-active medical devices", CEN/TC 215 "Respiratory and anaesthetic equipment", CEN/TC 251 "Medical informatics", CEN/TC 259 "Medical alarms and signals", CENELEC/TC 62 "Electrical equipment in medical practice", ISO/TC 20 "Aircraft and space vehicles", ISO/TC 22 "Road vehicles", ISO/TC 121 "Respiratory and anaesthetic equipment", ISO/TC 173 "Assistive products for persons with disability".	

6.2.4. CEN/TC 332 Laboratory equipment

General Information			
Creation Date	**1997**	**Laboratory equipment CEN/TC 332**	
Secretariat	DIN (Germany)		
Secretary	Dr. B. Winter		
Chairperson	Mr. T. A. Thiele		
Organizations in liaison	OIML, COWS of WASP, ASTM		
Subcommittees / Working groups	CEN/TC 332/WG 1 - Glass and plastics devices including volumetric instruments CEN/TC 332/WG 2 - Fittings and fixtures CEN/TC 332/WG 4 - Fume cupboards CEN/TC 332/WG 6 - Portable emergency shower devices CEN/TC 332/WG 7 - Micro-process engineering		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	Yes	**National delegates**	Mr. Gilles KLEIN Carrosserie Comes & Cie (CEN/TC 332/WG6)
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	12/11/2007
Scope	The CEN/TC 332 standardization work covers equipment for laboratories involved in chemical, physical and biological work. In general, equipment for laboratories can be divided into 3 main sections: - laboratory glass and plastics ware, - laboratory metrological and other electrical and non-electrical devices, - laboratory furniture, fittings and fixtures.
Executive summary	An important objective of this technical committee is the support of clinical and diagnostic laboratories in the fields of quality assurance of measurement equipment. However, the majority of the standardization activities are carried on in collaboration with and under the lead of the ISO/TC 48 "Laboratory equipment".

Work Program	
Published standards	50
Standards under development	2
	➢ prEN ISO 6556: Laboratory glassware - Filter flasks (ISO/DIS 6556:2011) ➢ Under drafting: Laboratory installations - Capture devices with articulated extract arm

Comments
The CEN/TC 332 works in close cooperation with ISO/TC 48 "Laboratory equipment". In addition, as some general laboratory equipment is also used in clinical and biotechnological laboratories A close cooperation exists with CEN/TC 140 "In vitro diagnostic medical devices", ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" and CEN/TC 233 "Biotechnology".

6.2.5. CENELEC/TC 62 Electrical equipment in medical practice

General Information			
Creation Date	-	**Electrical equipment in medical practice CENELEC/TC 62**	
Secretariat	BSI (United Kingdom)		
Secretary	Mr. Nick Bradfield		
Chairperson	Dr. Peter Linders		
Organizations in liaison	CEN/CLC MDD-AIMD-IVD, CCMC, EC, ETSI, NORMAPME		
Subcommittees / Working groups	JWG TC62 CEN/TC 251 – Task force on software related to the Medical Device Directive		
Participating Members 	Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom	**Observing Members** 	Bosnia and Herzegovina,
Total	25	**Total**	1
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Directive 2007/47/EC** of the European Parliament and of the Council of September 5th, 2007 amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC **Council Directive 93/42/EEC** of June 14th, 1993 concerning medical devices **Council Directive 90/385/EEC** of June 20th, 1990 on the approximation of the laws of the Member States relating to active implantable medical devices		
Standardization Mandates	**M/295:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/432**: Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/467:** Mandate to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots		
Business Plan			
Version	-		
Scope	The CENELEC TC/62 works on the establishment of harmonized standards regarding the manufacture of electrical equipment in human and veterinary medical practice in order to remove and prevent trade barriers. Medical practice in this context is comprised of surgery, dentistry, and other specialties. This technical committee works in close collaboration with the IEC/TC 62 on "Electrical equipment in medical practice".		
Executive Summary	-		

Work Program	
Published standards	197
Standards under development	39

Comments
In order to be fully in line with the scope of IEC/TC 62, the scope of the CENELEC TC/62 has been recently amended during the last meeting of the TC. It is not yet formally blessing by CENELEC BT but should be available in the following weeks.

6.2.6. ISO/TC 48 Laboratory equipment

General Information			
Creation Date	**1947**	**Laboratory equipment ISO/TC 48**	
Secretariat	DIN (Germany)		
Secretary	Dr. Burkhard Winter		
Chairperson	Mr. Tobias Anatol Thiele		
Organizations in liaison	ICG, WCO, WHO, WMO		
Subcommittees / Working groups	TC 48/SC 3 – Thermometers TC 48/SC 4 – Density measuring instruments TC 48/SC 5 – Quality of glassware TC 48/WG 3 – Micro-process engineering		
Participating Members 	China, Egypt, Finland, France, Germany, India, Italy, Kenya, Republic of Korea, Portugal, Russian Federation, Spain, Sri Lanka, USA, United Kingdom	**Observing Members** 	Australia, Austria, Barbados Belgium, Bosnia and Herzegovina, Chile, Croatia, Cuba, Czech Republic, Denmark, Estonia, Greece, Hong Kong/China, Indonesia, Islamic Republic of Iran, Ireland, Japan, Lebanon, Mongolia, Pakistan, Poland, Qatar, Romania, Serbia, South Africa, Switzerland, United Republic of Tanzania, Tunisia, Turkey, Ukraine
Total	15	**Total**	30
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	01/04/2008
Scope	The technical committee's activities cover the domain of the equipment for laboratories especially the devices and apparatus in the sections of: - laboratory glass and plastics ware, - laboratory metrological and other electrical and non-electrical devices, - laboratory furniture, fittings and fixtures. Apparatus and devices constructed for personal safety of persons working in laboratories are excluded from the scope of this technical committee.
Executive summary	Standards developed (or under development) by this technical committee are dedicated to the producers of laboratory equipment as well as the users of these devices and apparatus. The objectives are to guide the laboratory equipment manufacturer with respect to product safety liability, performance requirements requested by users, and legal

	authorities. From the users' side, it provides practical help in handling and calibrating the laboratory equipment, thus meeting specified quality criteria. It also assures the compatibility of equipment and materials from different manufacturers. The standards support legal authorities and manufacturers by specifying technically detailed requirements to fulfill basic legal requirements.
Work Program	
Published standards	110
Standards under development	1
	➢ ISO/FDIS 6556: Laboratory glassware - Filter flasks
Comments	
The standardization work provided by the ISO/TC 48 is also realized in close cooperation with partners such as International Organization of Legal Metrology (OIML), Commission on World Standards of the World Association of Societies of Pathology (COWS), World Association of Societies of (Anatomic and Clinical) Pathology (WASP), and other associations, and also with regional standardization organizations such as CEN. In addition, the developed standards are used by other ISO technical committees mainly working on the development of test standards, e.g. by ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" or ISO/TC 47 "Chemistry".	

6.2.7. ISO/TC 121 Anesthetic and respiratory equipment

General Information			
Creation Date	**1966**	**Anesthetic and respiratory equipment ISO/TC 121**	
Secretariat	ANSI (USA)		
Secretary	Mrs. Debra Milamed		
Chairperson	Dr. Julian M. Goldman		
Organizations in liaison	EIGA, IFRC, WFSA, WHO		
Subcommittees / Working groups	TC 121/SC 1 - Breathing attachments and anesthetic machines TC 121/SC 2 - Airways and related equipment TC 121/SC 3 - Lung ventilators and related equipment TC 121/SC 4 - Terminology and semantics TC 121/SC 6 - Medical gas systems TC 121/SC 8 - Suction devices for hospital and emergency care use TC 121/CAG - Chairman Advisory Group		
Participating Members 	Argentina, Australia, Austria, Belgium, Canada, China, Denmark, Finland, France, Germany, India, Islamic Republic of Iran, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Portugal, Russian Federation, Spain, Sweden, Switzerland, USA, United Kingdom	**Observing Members** 	Brazil, Cuba, Czech Republic, Egypt, Estonia, Greece, Hong Kong/China, Hungary, Iceland, Indonesia, Ireland, Norway, Poland, Romania, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, Thailand, Tunisia, Turkey, Ukraine
Total	25	**Total**	24
Participation of Luxembourg	Yes	**National delegates**	Mr. Philippe LARDENAIS CEODEUX S.A.
European Directives	-		
Standardization Mandates	-		
Business Plan			
Version	01/09/2004		
Scope	The ISO/TC 121 works on the standardization of anesthetic and respiratory equipment and supplies, related devices, and supply systems. It develops international standards for equipment used: - to administer anesthetic agents and medical gases to a patient, - to convey the correct anesthetic agents and medical gases to a device or a patient, - to conduct excess and expired gases safely away from a patient and operating room staff, - to monitor a patient undergoing treatment, - for respiratory therapy and care.		

Executive summary	The main objective of the ISO/TC 121 is to ensure the safety of the patient undergoing anesthesia and/or respiratory therapy and care. Other major safety-related aims are to safeguard the operator of the equipment, to ensure connectability and compatibility between devices, and to ensure devices are supplied with proper labeling, appropriate instructions for use, and technical performance data.
Work Program	
Published standards	84
Standards under development	33
	➢ ISO/DIS 5356-1: Anesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets ➢ ISO/FDIS 5356-2: Anesthetic and respiratory equipment - Conical connectors - Part 2: Screw-threaded weight-bearing connectors ➢ ISO/CD 5359 : Low-pressure hose assemblies for use with medical gases ➢ ISO/FDIS 5361: Anesthetic and respiratory equipment - Tracheal tubes and connectors ➢ ISO/FDIS 5366-1: Anesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults ➢ ISO/FDIS 5366-3: Anesthetic and respiratory equipment - Tracheostomy tubes - Part 3: Pediatric tracheostomy tubes ➢ ISO/DIS 5367: Anesthetic and respiratory equipment - Breathing sets and connectors ➢ ISO/WD 7396-1: Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum ➢ ISO 7396-1:2007/DAmd 3 ➢ ISO/CD 8836: Suction catheters for use in the respiratory tract ➢ ISO/CD 10079-1: Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements ➢ ISO/DIS 10079-2: Medical suction equipment - Part 2: Manually powered suction equipment ➢ ISO/DIS 10079-3: Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source ➢ ISO/AWI 10083: Oxygen concentrator supply systems for use with medical gas pipeline systems ➢ ISO 10524-3:2005/DAmd 1.2: Filtration and information to be supplied by the manufacturer ➢ ISO/CD 11197: Medical supply units ➢ ISO/AWI 13109: Medical gas pipeline systems - Essential safety requirements for tubes intended for compressed medical gases and vacuum in medical gas pipeline systems, anesthetic gas scavenging systems, and plume evacuation systems ➢ ISO/DIS 16571: Systems for evacuation of plume generated by medical devices ➢ ISO/CD 17256: Anesthetic and respiratory equipment - Respiratory therapy tubing and connectors ➢ ISO/CD 18082: Non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases ➢ ISO/DIS 27427: Anesthetic and respiratory equipment - Nebulizing systems and components ➢ IEC/CD 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests ➢ IEC/CD 60601-1-8: Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

	➢ IEC 60601-1-8:2006/DAmd 1 ➢ IEC/DIS 60601-1-12: Medical Electrical Equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment ➢ ISO 80601-2-13:2011/CD Amd 1 ➢ IEC 80601-2-30:2009/DAmd 1 ➢ ISO/NP 80601-2-62: Medical electrical equipment - Part 2-62: Particular requirements for basic safety and essential performance of medical supply units ➢ ISO/DIS 80601-2-67: Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment ➢ ISO/CD 80601-2-69: Medical Electrical Equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment ➢ ISO/CD 80601-2-70: Medical Electrical Equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnea breathing therapy equipment ➢ ISO/AWI 80601-2-72: Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients ➢ ISO/DIS 81060-2 : Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type
Comments	
To develop standards, the ISO/TC 121 works in close cooperation with the IEC/TC 62 "Electrical equipment in medical practice" and the CEN/TC 215 "Respiratory and anaesthetic equipment". Discussions are open with the IEC/TC62 about joint work on projects based on the principles in IEC 60601 Safety of electrical medical equipment.	

6.2.8. ISO/TC 172 Optics and photonics

General Information			
Creation Date	**1978**	**Optics and photonics ISO/TC 172**	
Secretariat	DIN (Germany)		
Secretary	Dipl.-Ing. Elisabeth Leitner		
Chairperson	Dr. Augustin Siegel		
Organizations in liaison	OIML		
Subcommittees / Working groups	TC 172/SC 1 - Fundamental standards TC 172/SC 3 - Optical materials and components TC 172/SC 4 - Telescopic systems TC 172/SC 5 - Microscopes and endoscopes TC 172/SC 6 - Geodetic and surveying instruments TC 172/SC 7 - Ophthalmic optics and instruments TC 172/SC 9 - Electro-optical systems		
Participating Members 	Australia, Austria, China, France, Germany, Islamic Republic of Iran, Italy, Japan, Kenya, Republic of Korea, Romania, Russian Federation, Switzerland, USA, United Kingdom	**Observing Members** 	Belarus, Belgium, Bulgaria, Canada, Croatia, Cuba, Czech Republic, Ethiopia, Finland, Hong Kong/China, Hungary, India, Indonesia, Ireland, Israel, Netherlands, Norway, Poland, Portugal, Serbia, Singapore, Slovakia, Spain, Sweden, Tunisia, Turkey, Ukraine
Total	15	**Total**	27
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	01/11/2004
Scope	The ISO/TC 172 sets standards for terminology, requirements, interfaces and test methods in the field of optics and photonics, considered as cross-sectional technologies. It includes complete systems, devices, instruments, ophthalmic optics, optical and photonic components, auxiliary devices and accessories, as well as materials. The range of products developed by the ISO/TC 172 covers sophisticated complete optical systems up to more simple semi-finished components. Specific items in the field of cinematography, photography, eye protectors, micrographics, fiber optics for telecommunication, electrical safety of optical elements, and general lighting are excluded from the scope of the technical committee.

Executive summary	The International Standards elaborated on by the ISO/TC 172 cover the market for optical systems and devices. Specifications of performance requirements, uniform terminology, test methods as well as safety standards are required. From a legal perspective, some of these standards may help to show conformity with the national or regional legal requirements, as with the European Directive on Medical Devices 93/42/EC.
Work Program	
Published standards	286
Standards under development	59
	Selection of standards under development having being referenced under the International Classification for Standards (ICS) code 11: Health care technology: ➢ ISO/DIS 8598-1.3: Optics and optical instruments - Focimeters - Part 1: General purpose instruments ➢ ISO/DIS 8600-1: Endoscopes - Medical endoscopes and endotherapy devices - Part 1: General requirements ➢ ISO/DIS 8600-7: Endoscopes - Medical endoscopes and endotherapy devices - Part 7: Basic requirements for medical endoscopes of water-resistant type ➢ ISO/DIS 8980-3: Ophthalmic optics - Uncut finished spectacle lenses - Part 3: Transmittance specifications and test methods ➢ ISO/DIS 9211-4: Optics and photonics - Optical coatings - Part 4: Specific test methods ➢ ISO/DIS 9394: Ophthalmic optics - Contact lenses and contact lens care products - Determination of biocompatibility by ocular study with rabbit eyes ➢ ISO/CD 10343: Ophthalmic instruments - Ophthalmometers ➢ ISO/DIS 10685-2: Ophthalmic optics - Spectacle frames and sunglasses electronic catalogue and identification - Part 2: Commercial information
Comments	
The ISO/TC 172 subcommittees SC 5 (Microscopes and endoscopes), SC 7 (Ophthalmic optics and instruments), and SC 9 (Electro-optical systems) are of particular interest because there are dedicated to the medical sector. Some of the work of ISO/TC 172 regarding test methods needs experimental validation and pre-research work. In the laser field covered by the SC 9, this research work was carried out under a European EUREKA Project CHOCLAB (Characterization of optical components and laser beams). Two sub-committees of ISO/TC 172 work in close working relationships with their European counterparts. Indeed, the SC 7 collaborates actively with the CEN/TC 170 "Ophthalmic Optics" and the SC 9 with CEN/TC 123 "Lasers and photonics".	

6.2.9. ISO/TC 173 Assistive products for persons with disabilities

General Information			
Creation Date	**1978**	**Assistive products for persons with disability ISO/TC 173**	
Secretariat	SIS (Sweden)		
Secretary	Mr. Olle Frick-Meijer		
Chairperson	Mr. Claes Tjäder		
Organizations in liaison	ANEC[31], CICR, EDANA, FMAC, ILO, ISPO, RI, WBU, WHO		
Subcommittees / Working groups	TC 173/SC 1 - Wheelchairs TC 173/SC 2 - Classification and terminology TC 173/SC 3 - Aids for ostomy and incontinence TC 173/SC 6 - Hoists for transfer of persons TC 173/SC 7 - Accessible design TC 173/WG 1 - Assistive products for walking TC 173/WG 9 - Assistive products for personal hygiene		
Participating Members 	Algeria, Australia, Austria, Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Islamic Republic of Iran, Ireland, Israel, Italy, Japan, Kenya, Republic of Korea, Netherlands, Norway, Romania, South Africa, Spain, Sweden, Switzerland, United Kingdom, Uruguay	**Observing Members** 	Chile, Costa Rica, Cuba, Czech Republic, Ecuador, Ethiopia, Greece, Hong Kong/China, Hungary, Iceland, India, Lithuania, Malaysia, New Zealand, Poland, Portugal, Russian Federation, Saudi, Serbia, Thailand, Trinidad and Tobago, Tunisia, Turkey, USA, Ukraine
Total	27	**Total**	25
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	01/02/2005
Scope	The primary goal of the ISO/TC 173 is to produce standards on assistive products for persons with disability. The main product categories covered by the standards produced by the ISO/TC 173 are wheelchairs, accessories to wheelchairs, walking aids, hoists for the transfer of disabled persons as well as aids for ostomy and incontinence.

[31] *ANEC: European Association for the Co-ordination of Consumer Representation in Standardization*

Executive summary	As already mentioned, the primary objective is to produce standards on assistive products for persons with disability. The main activity done by the ISO/TC 173 concerns the update and revision of existing standards dealing with walking aids and beds used for medical purposes.
Work Program	
Published standards	74
Standards under development	16
	➢ ISO/CD 7176-1: Wheelchairs - Part 1: Determination of static stability ➢ ISO/DIS 7176-3: Wheelchairs - Part 3: Determination of effectiveness of brakes ➢ ISO/DIS 7176-11: Wheelchairs - Part 11: Test dummies ➢ ISO/DIS 7176-16: Wheelchairs - Part 16: Resistance to ignition of upholstered parts - Requirements and test methods ➢ ISO 7176-19:2008/CD Amd 1 ➢ ISO/NP 7176-22: Wheelchairs - Part 22: Set-up procedures ➢ ISO/DIS 7176-25: Wheelchairs - Part 25: Batteries and chargers for powered wheelchairs - Requirements and test methods ➢ ISO/FDIS 7176-28: Wheelchairs - Part 28: Requirements and test methods for stair-climbing devices ➢ ISO/NP 9999: Assistive products for persons with disability - Classification and terminology ➢ ISO/FDIS 10542-1: Technical systems and aids for disabled or handicapped persons - Wheelchair tie down and occupant-restraint systems - Part 1: Requirements and test methods for all systems ➢ ISO/CD 10865-2: Wheelchair containment and occupant retention systems for accessible transport vehicles designed for use by both sitting and standing passengers - Part 2: Systems for forward-facing wheelchair-seated passengers Systems for forward facing wheelchair-seated passengers ➢ ISO/DIS 12505-1: Skin barrier for ostomy aids - Test methods - Part 1: Size, surface pH, and water-absorbency ➢ ISO/DTR 13570-2: Wheelchairs - Part 2: Typical values and recommended limits or dimensions, mass and maneuvering space as determined in ISO 7176-5 ➢ ISO/NP 17049-1: Accessible design - Methods of displaying braille signage - Part 1: Principles ➢ ISO/NP 17069: Accessible design - Consideration and assistive products for accessible meeting ➢ ISO/AWI 17966: Assistive products for personal hygiene
Comments	
The majority of work items directly under ISO/TC 173 concerns revision of existing standards dealing with walking aids and beds used for medical purposes. ISO/TC 173/SC1 has produced numerous standards dealing with aspects of wheelchairs ranging from nomenclature, test methods, and requirements for the wheelchair itself and wheelchair tie down and occupant-restraint systems. Approximately 25 standards dealing with aids for ostomy and continence have been produced by ISO/TC 173/SC3.	

6.2.10. ISO/TC 198 Sterilization of health care products

General Information			
Creation Date	**1990**	**Sterilization of health care products ISO/TC 198**	
Secretariat	ANSI (USA)		
Secretary	Mr. Joe Lewelling		
Chairperson	Dr. Eamonn V. Hoxey		
Organizations in liaison	AIII, EUCOMED, IAEA		
Subcommittees / Working groups	TC 198/WG 1 - Industrial ethylene oxide sterilization TC 198/WG 2 - Radiation sterilization TC 198/WG 3 - Moist heat sterilization TC 198/WG 4 - Biological indicators TC 198/WG 5 - Terminology TC 198/WG 6 - Chemical indicators TC 198/WG 7 - Packaging TC 198/WG 8 - Microbiological methods TC 198/WG 9 - Aseptic processing TC 198/WG 10 - Liquid chemical sterilization TC 198/WG 11 - General criteria for sterilization processes TC 198/WG 12 - Information for reprocessing of resterilizable devices TC 198/WG 13 - Washer-disinfectors TC 198/WG 14 - Dry heat sterilization		
Participating Members 	Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Egypt, Finland, France, Germany, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, Philippines, Portugal, Slovakia, South Africa, Spain, Sweden, Switzerland, Thailand, USA, United Kingdom	**Observing Members** 	Cuba, Estonia, Hong Kong/China, Hungary, India, Islamic Republic of Iran, Malaysia, Mauritius, Mongolia, Morocco, Norway, Poland, Romania, Russian Federation, Saudi Arabia, Serbia, Tunisia, Turkey, Ukraine, Uzbekistan
Total	30	**Total**	20
Participation of Luxembourg	Yes	**National delegates**	Mr. Thierry WAGNER DuPont de Nemours Luxembourg S.à r.l. (ISO/TC 198/WG7)
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	01/11/2004
Scope	The ISO/TC 198 is responsible for specifying requirements for sterilization processes, sterilizing equipment, washer-disinfectors, and ancillary products used in ensuring satisfactory sterilization of health care products.

Executive summary	The ISO/TC 198 works on standards for sterilization processes in order: - to ensure that sterilization processes employed by manufacturers or by healthcare service providers deliver an appropriate microbial lethality, - to provide guidance to assist those performing sterilization processes, - to provide a body of sterilization standards that can be adopted or adapted by national and regional regulatory authorities in order to ensure regulatory transparency and international harmonization of technical requirements for the sterilization of health care products.
Work Program	
Published standards	44
Standards under development	18
	➢ ISO/DIS 11135: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices ➢ ISO 11137-1:2006/DAmd 1: Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ➢ ISO/DIS 11137-2: Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose ➢ ISO/NP 11138-6: Sterilization of health care products - Biological Indicators - Part 6: Biological indicators for hydrogen peroxide vapor sterilization processes ➢ ISO/CD 11140-1: Sterilization of health care products - Chemical indicators - Part 1: General requirements ➢ ISO/NP 11140-6: Sterilization of health care products - Chemical indicators - Part 6: Class 2 indicators and process challenge devices for use in performance testing of steam sterilizers ➢ ISO 11607-1:2006/CD Amd 1: Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems ➢ ISO 11607-2:2006/CD Amd 1: Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes ➢ ISO/DTS 13004: Sterilization of health care products - Radiation - Substantiation of selected sterilization doses: Method VDmaxSD ➢ ISO 13408-1:2008/DAmd 1: Aseptic processing of health care products - Part 1: General requirements ➢ ISO 13408-6:2005/DAmd 1: Aseptic processing of health care products - Part 6: Isolator systems ➢ ISO/FDIS 13408-7: Aseptic processing of health care products - Part 7: Alternative processes for atypical medical devices and combination products ➢ ISO 15883-1:2006/DAmd 1: Washer-disinfectors - Part 1: General requirements, terms and definitions and tests ➢ ISO/WD 15883-7: Washer-disinfectors - Part 7: Requirements and tests for general purpose washer-disinfectors employing chemical disinfection for bedframes, bedside tables, transport carts, containers, surgical tables, furnishings and surgical clogs ➢ ISO/DTS 16775: Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2 ➢ ISO/AWI 17210: Test method to demonstrate the suitability of a medical device simulator during steam sterilization - Medical device simulator testing ➢ ISO/DTS 17665-3: Sterilization of health care products - Steam sterilization - Part 3: Product families ➢ ISO/AWI 18362: Processing of cell-based health care products
Comments	
The ISO/TC 198 works in close collaboration with CEN/TC 102 “Sterilizers for medical devices” and with CEN/TC 204 “Sterilization of medical devices”.	

6.2.11. IEC/TC 62 Electrical equipment in medical practice

General Information			
Creation Date	**1968**	**Electrical equipment in medical practice IEC/TC 62**	
Secretariat	Germany		
Secretary	Mr. N. Bischof		
Chairperson	Mr. R. I. Godinez		
Organizations in liaison	COCIR, GHTF		
Subcommittees / Working groups	TC62/SC 62A - Common aspects of electrical equipment used in medical practice TC62/SC 62B - Diagnostic imaging equipment TC62/SC 62C - Equipment for radiotherapy, nuclear medicine and radiation dosimetry TC62/SC 62D - Electromedical equipment TC62/AG 1 CAG - Chairman Advisory Group TC62/AG SNAG - Software and Networks Advisory Group		
Participating Members 	Belgium, Brazil, Canada, China, Denmark, Finland, France, Germany, Hungary, India, Ireland, Italy, Japan, Republic of Korea, Malaysia, Netherlands, Norway, Pakistan, Portugal, Romania, Russian Federation, South Africa, Spain, Sweden, Switzerland, USA, United Kingdom	**Observing Members** 	Australia, Austria, Bulgaria, Croatia, Czech Republic, Greece, Indonesia, Iran, Israel, New Zealand, Poland, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, Ukraine
Total	27	**Total**	17
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	23/09/2011
Scope	This technical committee works on standards concerning electrical equipment, electrical systems and software used in healthcare. It covers safety and performance for specific healthcare products such as diagnostic imaging, radiotherapy, nuclear medicine, radiation dosimetry, electro-medicine, anesthesia, critical care, surgery, artificial respiration and pediatrics.
Executive summary	The IEC/TC 62 develops specific programs for particular standards according to the technical and healthcare innovations and also to maintain up-to-date standards in the area of mature technologies. The IEC 60601 family of standards was developed by the IEC/TC 62. It constitutes the essential foundation for standards for medical electrical equipment and systems. The main objective of this work was to produce a test standard that would ensure the basic safety of electro-medical devices.

Work Program	
Published standards	4
	➢ IEC 60601-1-4 (Ed. 1.1 and 1.0): Medical electrical equipment – Part 1-4: General requirements for safety – Collateral Standard: Programmable electrical medical systems ➢ IEC 60601-1-4-am1 (Ed. 1.0 and 1.0): Amendment 1 - Medical electrical equipment - Part 1: General requirements for safety - 4. Collateral standard: Programmable electrical medical systems ➢ IEC/TR 60788 (Ed. 2.0): Medical electrical equipment - Glossary of defined terms ➢ ISO 80601-2-13: Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anesthetic workstation
Standards under development	0

Comments
In the future, healthcare software should gain more importance in the IEC/TC 62 work. Close cooperation with other committees and organizations in the software and IT network sector such as ISO/TC 215 "Health informatics" or Digital imaging and communication in medicine (DICOM) will be reinforced. In addition, this technical committee works also in close collaboration with the CENELEC/TC 62 on "Electrical equipment in medical practice". This technical committee has also some internal liaisons with IEC/TC 87 "Ultrasonics" and IEC/TC 96 "Transformers, reactors, power supply units and combinations thereof".

6.3. SUBSECTOR 3 – MEDICAL SERVICES

The sector of healthcare services concerns the provision and supply of medical services. It encompasses all services delivered, performed by health personnel or other people under the supervision of these personnel to promote, maintain, improve, or restore the general mental or physical well-being of a patient.

The needs for medical services in Europe and in the rest of the world have increased drastically in recent years. One cause of this increase is an ageing society that represents a major demographic challenge for the coming years and requires the development of efficient and qualitative healthcare services.

In addition, health services are often considered to be of great economic relevance. In 2010, this sector (with the social sector) employed about 11% of the total European workforce. The medical services sector is also considered to be a dynamic sector that has the potential to create further jobs. Indeed, the health and social care sector has been a key driver of the expansion of the services sector since 2000 (up to 2.3 million jobs). Conscious of these issues, the European Commission supports the development of a Community framework for safe, high quality and efficient health services.[32]

In Luxembourg, during the period 1995-2007, the employment rate of the economic sector "*services de santé et d'action sociale*", registered solid growth, increasing from 6.3% to 7.7% of the overall national employment (Statec – National Accounts). The dynamism of this sector has to be linked to constant development of new medical technologies and the growth of the demands of healthcare supported by an aging population[33]. It also appears that this sector is moving progressively towards activities with higher added value.

Thus, the medicine services sector needs to be improved in order to be able to meet the needs and expectations of the health customers and healthcare professionals. If most healthcare services are still delivered inside medical premises, the development of eHealth technologies, for example, is strongly modifying the world of medical services.

However, it is important to keep in mind that standardization activities in the medical services sector have to fully respect the distribution of competences between the European Union and the Member States as laid down in the Treaty on the Functioning of the European Union. Indeed, it remains exclusively for the EU Member States to define the fundamental principles of their social security, vocational training and health systems and to shape the framework conditions for the management, financing, organization and delivery of the services supplied within those systems.

For this subsector, 5 European standardization technical committees were identified as interesting.

[32] White Paper of the European Commission "Together for Health: A Strategic Approach for the EU 2008-2013", COM (2007) 630 final (http://ec.europa.eu/health/ph_overview/Documents/strategy_wp_en.pdf)

[33] "*La médecine personnalisée: Un moteur pour l'amélioration et le développement du secteur de la santé*", Laurent Probst and Erica Monfardini, Phramaceutical sector Experts in PwC Luxembourg, article published in "*Forum Entreprises*", October 2009, pp. 31-32.

6.3.1. CEN/TC 362 Project Committee - Healthcare services - Quality management system

General Information			
Creation Date	**2007**	**Project Committee Healthcare services - Quality management systems CEN/TC 362**	
Secretariat	SIS (Sweden)		
Secretary	Mrs. C. Stange		
Chairperson	Mr. O. Edhag		
Organizations in liaison	-		
Subcommittees / Working groups	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		
Business Plan			
Version	-		
Scope	-		
Executive summary	-		
Work Program			
Published standards	2		
	➢ CEN/TR 15592: Health services - Quality management systems - Guide for the use of EN ISO 9004:2000 in health services for performance improvement ➢ CEN/TS 15224: Health services - Quality management systems - Guide for the use of EN ISO 9001:2000		
Standards under development	1		
	➢ FprEN 15224: Health care services - Quality management systems - Requirements based on EN ISO 9001:2008		
Comments			
-			

6.3.2. CEN/TC 394 Project Committee - Services of chiropractors

General Information			
Creation Date	**2009**	**Project Committee Services of Chiropractors CEN/TC 394**	
Secretariat	ASI (Austria)		
Secretary	Dipl.-Ing. J. Winkler		
Chairperson	Mr. P. Druart		
Organizations in liaison	-		
Subcommittees / Working groups	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	2009
Scope	The CEN/TC 394 works on the standards development of requirements and recommendations for health care services provided by chiropractors to ensure quality practices and patient safety.
Executive summary	Chiropractic is a primary contact healthcare profession concerned with disorders of the neuromusculoskeletal system. This technical committee focuses its standardization activities on the provision of chiropractic services. It aspires to set standards that provide optimum levels of patient management, safety, clinical effectiveness and cost effectiveness. It also defines a level of education consistent with producing chiropractors that are competent to comply with the standard.

Work Program	
Published standards	1
	➢ EN 16224:2012: Healthcare provision by chiropractors
Standards under development	0

Comments
This technical committee is relatively new and released its first standard in June 2012.

6.3.3. CEN/TC 403 Project Committee - Aesthetic surgery services

General Information			
Creation Date	**2010**	**Project Committee Aesthetic surgery services CEN/TC 403**	
Secretariat	ASI (Austria)		
Secretary	Dr. K. Grün		
Chairperson	Mr. J. Umschaden		
Organizations in liaison	-		
Subcommittees / Working groups	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	2010
Scope	The CEN/TC 403 works on the development of European Standard setting requirements for aesthetic services to patients. It will take into account general and ethical principles relating to these services – before, during, and after intervention – provided by private facilities.
Executive summary	

Work Program	
Published standards	0
Standards under development	1
	➢ prEN 16372: Aesthetic surgery services

Comments
This technical committee is relatively new and works on the development of a specific standard that is currently under approval and should be released in 2013.

6.3.4. CEN/TC 414 Project Committee - Services of osteopaths

General Information			
Creation Date	**2011**	**Project Committee Services of Osteopaths CEN/TC 414**	
Secretariat	ASI (Austria)		
Secretary	Dipl.-Ing. J. Winkler		
Chairperson	Mr. J. Bailey-Teyletche		
Organizations in liaison	FORE, EFO		
Subcommittees / Working groups	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	2011
Scope	Created in October 2011, the CEN/TC 414 "Project Committee - Services of osteopaths" works in the area of osteopath services.
Executive summary	The CEN/TC 414 works on the development of standards in relation of the services of osteopaths. This need has been identified at the European level. Definitions of requirements and of the level of osteopathic service provision are essential in order to provide a safe environment for patients. This would also give patients and the public the information they need to know what to expect from treatment and create a level playing field for osteopaths in Europe.

Work Program	
Published standards	0
Standards under development	1
	➢ Standard under drafting: Osteopathic healthcare provision

Comments
This technical committee is relatively new and works on the development of a specific standard that is currently under drafting. A first version should be ready in 2015.

6.3.5. CEN/WS 068 CEN Workshop - Health care services: Basic quality criteria for health checks

General Information			
Creation Date	**2011**	**CEN Workshop Health care services: Basic quality criteria for health checks CEN/WS 068**	
Secretariat	NEN (Netherlands)		
Secretary	Mrs. Ir Marlou Bijlsma		
Chairperson	Mrs. A. Cecile J.W. Janssens		
Organizations in liaison	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	02/12/2011
Scope	The main objective of this workshop is to achieve consensus on the basic principles of quality criteria for health checks. Quality criteria for health checks aim: - to encourage good practices in prevention and early detection of health risks, - to protect individuals against the risks of unsound health checks, - to allow clients to make responsible choices about health checks.
Executive summary	Based on the specific actions of the Executive Agency for Health and Consumers of the European Commission and on an initiative of the Government of the Netherlands, a joint European action has been initiated focusing on the development of basic quality criteria for health checks. Hence, a CEN Workshop Agreement (CWA) on 'Basic quality criteria for health checks' was launched.

Work Program	
Published standards	0
Publications under development	1
	➢ WS068001: Publication CEN Workshop Agreement "Health care services - Quality criteria for health checks"

Comments
A draft Report on Quality criteria for health checks and internal reviewing period should be available for comments in November 2012. The next CEN Workshop Plenary meeting is planned in March 2013.

6.4. SUBSECTOR 4 – DIAGNOSTICS

The diagnostics sector derives from the medical devices sector and encompasses the biological analysis, molecular diagnostics, or in vitro diagnostic tests.
To give some more detailed definitions, in vitro diagnostics (IVD) tests are defined by the Global Harmonization Task Force as medical devices intended for the in vitro examination of specimens including blood, urine and tissue donations derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. Regarding molecular diagnostics, the American National Cancer Institute described this as the process of identifying a disease by studying molecules, such as proteins, DNA, and RNA, in a tissue or fluid.

This specific subsector is of high interest and in full development at the national and international levels. The diagnostic field, situated at the intersection between technology and biomedicine, is a niche offering interesting opportunities for research and economic activities. Aware of this opportunity, the government of Luxembourg developed in 2007 "The Luxembourg Health Sciences and Technologies Action Plan", a commitment to invest in biosciences and position Luxembourg as a bioscience hub in Europe.

Following this decision, a major project was initiated in June 2008 to develop specific expertise in the field of molecular and in vitro diagnostics. This project, planned for 5 years, runs in close collaboration with 3 American Research Institutes: the Translational Genomics Research Institute (TGen), the Institute for Systems Biology (ISB) and the Partnership for Personalized Medicine (PPM).

This initiative has subsequently resulted in the creation of two key infrastructures: the Integrated BioBank of Luxembourg (IBBL) and the Luxembourg Centre for Systems Biomedicine (LCSB). The IBBL is a biobanking and biotechnology foundation designed to collect, store and analyze biological samples and associated data in order to make available this information to research organizations investigating new treatments for diseases. The LCSB is making a link between biology and medical research systems in order to increase the understanding of principal mechanisms of disease pathogenesis and for developing new tools in diagnostics and therapy.

For this subsector, 9 standardization technical committees were identified as interesting (6 at a European level and 3 at an international level).

6.4.1. CEN/TC 140 In vitro diagnostic medical devices

General Information			
Creation Date	**1988**	**In vitro diagnostic medical devices CEN/TC 140**	
Secretariat	DIN (Germany)		
Secretary	Mr. R. Schmidt		
Chairperson	Dr. M. Thein		
Organizations in liaison	CLSI, COWS of WASP, EDMA, EQALM, ICSH, IFCC, ISTH		
Subcommittees / Working groups	CEN/TC 140/WG 3 - Quality management in the medical laboratory CEN/TC 140/WG 5 - Specimen containers		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Directive 98/79/EC** of the European Parliament and of the Council of October 27th, 1998 on in vitro diagnostic medical devices **Regulation (EC) No 765/2008** of the European Parliament and of the Council of July 9th, 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93		
Standardization Mandates	**M/252** Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices **M/320** Mandate to CEN concerning the development of European standards relating to medical devices (Subject: breast implants) **M/321** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (Subject: sub-categories for medical devices) **M/384** Mandate to CEN concerning the development of European standards relating to colour coding systems intended for specimen receptacles used for in vitro diagnostic medical devices		
Business Plan			
Version	10/05/2010		
Scope	The scope of the CEN/TC 140 is to develop and maintain up-to-date standards focusing on in vitro diagnostic (IVD) medical devices used with regard to safety, health protection, performance characteristics, and authorization procedures.		
Executive summary	The standards developed by the CEN/TC 140 should: - assist manufacturers of IVD products in demonstrating fulfillment of the applicable requirements of the Directive 98/79/EC and provide manufacturers, notified bodies, test houses with a clear route to CE marking, - contribute to the elimination of trade barriers and favor the global market, - provide agreed test methods and improve the quality of testing.		

Work Program	
Published standards	30
Standards under development	4
	➢ prEN ISO 15189: Medical laboratories - Requirements for quality and competence (ISO/DIS 15189:2011) ➢ prEN ISO 19001: In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology (ISO/DIS 19001:2010) ➢ prEN ISO 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO/DIS 15197:2011) ➢ prEN ISO 16256: Clinical laboratory testing and in vitro diagnostic test systems - Reference method for testing the in vitro activity of antimicrobial agents against yeast of fungi involved in infectious diseases (ISO/DIS 16256:2011)

Comments
The technical committee CEN/TC 140 developed a close collaboration with other European technical committees as the CEN/TC 204 "Sterilization of medical devices", the CEN/TC 257 "Symbols and information provided with medical devices and nomenclature for regulatory data exchange", the CEN Advisory Board for Health Standards (ABHS), the CENELEC/BTTF 88-1 "Automatic operating analytical appliances including In-Vitro-Diagnostic Medical Devices" and IEC/TC 66 "Safety of measuring, control and laboratory equipment" with regard to the standards EN 61010-2-081 "Safety requirements for electrical equipment for measurement, control and laboratory use" and EN 61010-2-101 "Safety requirements for electrical equipment for measurement, control and laboratory use". Under the Vienna Agreement, the standardization activities of the CEN/TC 140 is also in liaison with the ISO/TC 48 "Laboratory equipment", the ISO/TC 76 "Transfusion, infusion and injection equipment for medical and pharmaceutical use", the ISO/TC 210 "Quality management and corresponding general aspects for medical devices" and the ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems".

6.4.2. CEN/TC 216 Chemical disinfectants and antiseptics

General Information			
Creation Date	**1989**	**Chemical disinfectants and antiseptics CEN/TC 216**	
Secretariat	AFNOR (France)		
Secretary	Mrs. P. Blazejewska		
Chairperson	Dr. J. Gebel		
Organizations in liaison	EC, EFTA		
Subcommittees / Working groups	CEN/TC 216/WG 1 - Human medicine CEN/TC 216/WG 2 - Veterinary use CEN/TC 216/WG 3 - Food hygiene and domestic and institutional use		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Council Directive 93/42/EEC** of June 14th, 1993 concerning medical devices **Directive 98/8/EC** of the European Parliament and of the Council of February 16th, 1998 concerning the placing of biocidal products on the market		
Standardization Mandates	**M/252:** Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices **M/295:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices **M/320:** Mandate to CEN concerning the development of European standards relating to medical devices (breast implants) **M/321:** Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices (sub-categories for medical devices) **M/322:** Mandate to CEN, CENELEC and ETSI for the alignment of medical devices standards to the Radio and Telecommunications Terminal Equipment (RTTE) Directive **M/332:** Mandate to CEN/ CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of EN1970:2000 "beds for the disabled" **M/333:** Mandate to CEN concerning flammability of mattresses and bed bases for medical purposes **M/342:** Mandate to CEN/CENELEC concerning the development of European standards relating to medical devices (hyperbaric chambers for medical purposes) **M/432:** Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/433:** Mandate to CEN and CENELEC within the framework of Directive 2007/47/EC, amending Directive 93/42/EEC relating to medical devices concerning graphical symbols for use in the labeling of medical devices containing phthalates **M/467:** Mandate to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots		

Business Plan	
Version	20/12/2005
Scope	The standards developed by the CEN/TC 216 have been developed to evaluate if a product does or does not have antimicrobial (fungicidal, bactericidal, mycobactericidal, sporicidal, virucidal) activity. These standards will allow for the evaluation of the effectiveness of biocides that includes the antimicrobial activity of an active substance or product.
Executive summary	Directive 98/8/EC concerning the placing of biocidal products on the market, covers a range of biocidal products including Human hygiene biocidal products, Private area and public health area disinfectants, Veterinary hygiene biocidal products and Food and feed area disinfectants. The objectives of the CEN/TC 216 are therefore to elaborate standards to qualify these products depending on: - their activity (fungicidal, bactericidal, mycobactericidal, sporicidal, virucidal), - their applications (human medicine, veterinary use, food hygiene and domestic and institutional use).
Work Program	
Published standards	29
Standards under development	16
	➢ prEN 1499 rev: Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2) ➢ prEN 1500 rev: Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2) ➢ prEN 13697 rev: Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2, step 2) ➢ prEN 13624: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1) ➢ prEN 16437: Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step2) ➢ prEN 14476 rev: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1) ➢ Under drafting: Chemical disinfectants and antiseptics - Chemical-thermal linen disinfection - Test method and requirements (phase 2, step 2) ➢ prEN 12353 rev: Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal activity ➢ FprEN 14204: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1) ➢ FprEN 14349: Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2) ➢ prEN 16438: Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and

	antiseptics used in the veterinary area on non-porous surfaces without mechanical action - (phase 2, step 2) ➢ EN 1650:2008/prA1: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1) ➢ Under drafting: Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal activity on non-porous surfaces with mechanical action employing wipes or mops in the medical area - Test method and requirements (phase 2, step 2) ➢ prEN 14885 rev: Chemical disinfectants and antiseptics - Application of European standards for chemical disinfectants and antiseptics ➢ prEN 12791 rev: Chemical disinfectants and antiseptics - Surgical hand disinfection - Test method and requirement (phase 2/step 2) ➢ prEN 14675 rev: Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)
Comments	
In order to avoid overlapping work with existing bodies, collaborations are established with the CEN/TC 55 "Dentistry", the CEN/TC 102/WG 8 "Sterilizers for medical purposes – Performance requirements and testing for washer-disinfectors", the CEN/TC 204/WG 10 "Sterilization of medical devices – Information for re-processing of resterilizable devices", the CEN/TC 243 "Clean-room technology" and the CEN/TC 316 "Medical devices utilizing tissues".	

6.4.3. CEN/TC 347 Methods for analysis of allergens

General Information			
Creation Date	**2003**	**Methods for analysis of allergens CEN/TC 347**	
Secretariat	DS (Denmark)		
Secretary	Mrs. L. Skjerning		
Chairperson	Mr. D. J. Schakel		
Organizations in liaison	-		
Subcommittees / Working groups	CEN/TC 347/WG 1 - Metals CEN/TC 347/WG 2 - Plastics and rubber chemicals CEN/TC 347/WG 4 - Fragrances and colophony		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Regulation (EC) No 1907/2006** of the European Parliament and of the Council of December 18th, 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC		
Standardization Mandates	-		

Business Plan	
Version	06/11/2009
Scope	The CEN/TC 347 is developing standards for analytical methods for determination of allergenic chemical in materials and products. Methods can be established for the testing of any material. However, the technical committee focuses only on potential allergens in materials identified to cause health problems in the European community. Thus, the following materials and products will not be considered by CEN/TC 347: - allergens in food, - medicinal products, - natural latex proteins or other proteins, - testing of sensitizing potential of allergens.
Executive summary	The creation of the CEN/TC 347 was based on the review carried by CEN/BT/WG 132 that identified 56 chemicals through a review of 69 selected allergens. Therefore, the CEN/TC 347 develops standards covering these 56 substances through different working groups dedicated to specific materials as metals, preservatives, plastic and rubber chemicals, fragrances and colophony.

Work Program	
Published standards	3
	➢ EN 12472:2005+A1:2009: Method for the simulation of wear and corrosion for the detection of nickel release from coated items ➢ EN 1811:2011: Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin ➢ EN 1811:2011/AC:2012: Reference test method for release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles intended to come into direct and prolonged contact with the skin
Standards under development	1
	➢ FprEN 16274: Methods for analysis of allergens - Quantification of suspected fragrance allergens in consumer products - Step 1: GC analysis of ready-to-inject sample
Comments	
-	

6.4.4. CEN/TC 367 Breath-alcohol testers

General Information			
Creation Date	**2008**	**Breath-alcohol testers CEN/TC 367**	
Secretariat	AFNOR (France)		
Secretary	Mrs. F. Saillet		
Chairperson	Mrs. S. Vaslin-Reimann		
Organizations in liaison	-		
Subcommittees / Working groups	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		
Business Plan			
Version	-		
Scope	The CEN/TC 367 works on standards in the field of breath-alcohol testers to be used for screening. The standards developed include procedures for type testing, performance requirements, and requirements for marking, labeling and operating instructions.		
Executive summary	-		
Work Program			
Published standards	1		
	➢ EN 15964:2011: Breath alcohol test devices other than single use devices - Requirements and test methods		
Standards under development	1		
	➢ FprEN 16280: Breath alcohol test devices for general public - Requirements and test methods		
Comments			
-			

6.4.5. CENELEC/BTTF 116-2 Alcohol interlocks

General Information			
Creation Date	**2004**	**Alcohol interlocks CLC/BTTF 116-2**	
Secretariat	DIN (Germany)		
Secretary	Mr. Jürgen Schütz		
Chairperson	Mr. Johannes Lagois		
Organizations in liaison	EC, NORMAPME		
Subcommittees / Working groups	-		
Participating Members 	Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland	**Observing Members** 	-
Total	22	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	-
Scope	The CLC/BTTF 116-2 works on the development of European standards for alcohol interlocks.
Executive summary	-

Work Program	
Published standards	3
	➢ EN 50436-2:2007: Alcohol interlocks - Test methods and performance requirements - Part 2: Instruments having a mouthpiece and measuring breath alcohol for general preventive use ➢ EN 50436-1:2005: Alcohol interlocks - Test methods and performance requirements - Part 1: Instruments for drink-driving-offender programs ➢ CLC/TR 50436-3:2010: Alcohol interlocks - Test methods and performance requirements - Part 3: Guidance for decision makers, purchasers and users
Standards under development	5
	➢ prEN 50436-2:2006: Alcohol interlocks - Test methods and performance requirements - Part 2: Instruments having a mouthpiece and measuring breath alcohol for general preventive use

	➢ prEN 50436-2:2007: Alcohol interlocks - Test methods and performance requirements - Part 2: Instruments having a mouthpiece and measuring breath alcohol for general preventive use ➢ CLC/FprTR 50436-3:2010: Alcohol interlocks - Test methods and performance requirements - Part 3: Guidance for decision makers, purchasers and users ➢ prEN 50436-3:2008: Alcohol interlocks - Test methods and performance requirements - Part 3: Guidance for decision makers, purchasers and users ➢ prEN 50436-4:2007: Alcohol interlocks -Test methods and performance requirements - Part 4: Connectors for the electrical connection between the alcohol interlock and the vehicle
Comments	
-	

6.4.6. CEN/WS 055 Guidance Document for CWA 15793:2008 Laboratory Biorisk Management Standard

General Information			
Creation Date	**2010**	**Guidance Document for CWA 15793:2008 Laboratory Biorisk Management Standard CEN/WS 055**	
Secretariat	NEM (The Netherlands)		
Secretary	Mr. M. De Vreeze		
Chairperson	Dr. S. Wagener		
Organizations in liaison	-		
Subcommittees / Working groups	-		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	31/01/2011
Scope	The CEN/WS 055 was active through the CEN Workshop Agreement (CWA) 15793:2008. The work developed from this workshop ended with the first internationally recognized management-system approach to specifically address biological hazards associated with laboratories.
Executive summary	The CEN/CWA 15793:2008 was proposed by six organizations: European Biological Safety Association (EBSA), Global Partnership Program (GPP), National Microbiology Laboratory (NML), International Centre for Infectious Diseases (ICID) and American Biological Safety Association (ABSA). They started their activities on February 2010 and released their guidance document in 2012. It provides a structured approach for an organization to effectively and efficiently address issues relating to biosafety and biosecurity while providing opportunities for operational improvements.

Work Program	
Published standards	1
	➢ CWA 16393:2012: Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008
Standards under development	0

Comments
The activities of the CEN/WS 055 on laboratory biorisk management have been finalized through the release of the CWA 16393:2012 / Laboratory biorisk management - Guidelines for the implementation of CWA 15793:2008. The CEN/WS 055 worked in close collaboration with CEN Workshop 53 on "Biosafety Professional Competence" (BSP) dealing with biosafety and biosecurity and also with ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" and the WG 1 of the CEN/TC 316 "Medical devices utilizing tissues".

6.4.7. ISO/TC 194 Biological evaluation of medical devices

General Information			
Creation Date	**1988**	**Biological evaluation of medical devices ISO/TC 194**	
Secretariat	DIN (Germany)		
Secretary	Dipl.-Ing. Karl Wenzelewski		
Chairperson	Dr. Albrecht Poth		
Organizations in liaison	EUCOMED, OECD, OIE, WHO		
Subcommittees / Working groups	TC 194/WG 1 - Systematic approach to biological evaluation and terminology TC 194/WG 2 - Degradation aspects related to biological testing TC 194/WG 3 - Animal protection aspects TC 194/WG 4 - Clinical investigations of medical devices in humans TC 194/WG 5 - Cytotoxicity TC 194/WG 6 - Mutagenicity, carcinogenicity and reproductive toxicity TC 194/WG 7 - Systemic toxicity TC 194/WG 8 - Irritation, sensitization TC 194/WG 9 - Effects on blood TC 194/WG 10 - Implantation TC 194/WG 11 - Allowable limits for leachable substances TC 194/WG 12 - Sample preparation and reference materials TC 194/WG 13 - Toxicokinetic study TC 194/WG 14 - Material characterization TC 194/WG 15 - Strategic approach to biological assessment TC 194/WG 16 - Pyrogenicity TC 194/WG 17 - Nanomaterials TC 194/SC 1 - Tissue product safety		
Participating Members 	Australia, Austria, Belgium, Brazil, Canada, China, Denmark, France, Germany, Ireland, Italy, Japan, Republic of Korea, Malaysia, Netherlands, Norway, Russian Federation, Spain, Sweden, Switzerland, USA, United Kingdom	**Observing Members** 	Argentina, Cuba, Czech Republic, Estonia, Finland, Hong Kong/China, Hungary, Iceland, India, Islamic Republic of Iran, Jamaica, Mauritius, Mongolia, Philippines, Poland, Portugal, Romania, Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, Thailand, Turkey, Ukraine
Total	22	**Total**	25
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	04/11/2005
Scope	The main focus of the ISO/TC 194 is the standardization of biological evaluation and the clinical investigation of medical devices and materials.
Executive summary	This technical committee develops standards that are internationally applicable for the evaluation and testing of medical and dental devices that come into contact with the human body. Therefore it contributes indirectly to public health and well-being by developing standards for medical devices. These standards ensure that manufacturers' products do not compromise the biological and clinical safety of patients. The current set of standards and standards being prepared can be divided into two parts, one part for the biological evaluation (ISO 10993-1) and one part for the clinical investigation (ISO 14155-1).
Work Program	
Published standards	31
Standards under development	2
	➢ ISO/DIS 10993-3: Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity ➢ ISO/AWI 10993-6: Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
Comments	
The ISO/TC 194 works in liaison with numerous other ISO technical committees as the following: TC 76, TC 84, TC 106, TC 150, TC 150/SC 2, TC 150/SC 7, TC 172, TC 173, TC 198, TC 210 and TC 215. In parallel, it develops a close cooperation with CEN/TC 206 "Biocompatibility of medical and dental materials and devices", CEN/TC 258 "Clinical investigation of medical devices" and CEN/TC 316 "Medical devices utilizing tissues".	

6.4.8. ISO/TC 209 Cleanrooms and associated controlled environments

General Information			
Creation Date	**1993**	**Cleanrooms and associated controlled environments ISO/TC 209**	
Secretariat	ANSI (USA)		
Secretary	Mr. Robert L. Mielke		
Chairperson	Dr. David Ensor		
Organizations in liaison	ICCCS		
Subcommittees / Working groups	TC 209/WG 1 - Airborne particulate cleanliness classes TC 209/WG 2 - Biocontamination TC 209/WG 3 - Metrology and test methods TC 209/WG 4 - Design and construction TC 209/WG 5 - Cleanroom operation - STANDBY TC 209/WG 6 - Terms, definitions and units TC 209/WG 7 - Enhanced cleaning devices TC 209/WG 8 - Chemical contamination TC 209/WG 9 - Clean surfaces TC 209/WG 10 - Nanotechnology TC 209/WG 11 - Assessment of suitability of equipment and materials for cleanrooms TC 209/WG 12 - Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications		
Participating Members 	Algeria, Australia, Belgium, Brazil, China, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Republic of Korea, Netherlands, Norway, Philippines, Portugal, Russian Federation, Sweden, Switzerland, USA, United Kingdom	**Observing Members** 	Argentina, Austria, Bosnia and Herzegovina, Bulgaria, Cuba, Czech Republic, Egypt, Hungary, India, Islamic Republic of Iran, Jamaica, Kenya, Malaysia, Poland, Romania, Saudi Arabia, Serbia, South Africa, Thailand, Turkey, Ukraine
Total	22	**Total**	21
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	02/11/2004
Scope	The ISO/TC 209 standardization activities focus on equipment, facilities, and operational methods for cleanrooms and associated controlled environments. This includes procedural limits, operational limits and testing procedures to achieve desired attributes to minimize micro contamination.
Executive summary	The primary objectives and priorities in the work of ISO/TC 209 are to develop a family of international cleanroom standards to address the specific areas of classification of air cleanliness. In addition, standard should detail specifications for testing and monitoring to prove cleanliness, develop test methods for evaluation of

	cleanroom performance. It should also propose requirements in the design and construction of cleanrooms and the operation of cleanroom facilities. Finally, the issues regarding the separative devices (clean air hoods, glove boxes, isolators, and minienvironments), the biocontamination control in cleanrooms and molecular contamination control in cleanrooms should also be addressed in the standards developed by the ISO/TC 209.
Work Program	
Published standards	11
Standards under development	8
	➢ ISO/DIS 14644-1: Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration ➢ ISO/DIS 14644-2: Cleanrooms and associated controlled environments - Part 2: Specifications for monitoring and periodic testing to prove continued compliance with ISO 14644-1 ➢ ISO/DIS 14644-8: Cleanrooms and associated controlled environments - Part 8: Classification of air cleanliness by chemical concentration ➢ ISO/FDIS 14644-9.2: Cleanrooms and associated controlled environments - Part 9: Classification of surface cleanliness by particle concentration ➢ ISO/DIS 14644-10: Cleanrooms and associated controlled environments - Part 10: Classification of surface cleanliness by chemical concentration ➢ ISO/NP 14644-12: Cleanrooms and associated controlled environments - Part 12: Classification of air cleanliness by nanoscale particle concentration ➢ ISO/NP 14644-13: Cleanrooms and associated controlled environments - Part 13: Cleaning of surfaces to achieve defined levels of cleanliness in terms of particle and chemical classifications ➢ ISO/NP 17910: Assessment of suitability of equipment and materials for cleanrooms
Comments	
Liaison members of ISO/TC 209 are as follows: ISO/TC 146 "Air quality", ISO/TC 198 "Sterilisation of healthcare products", ISO/TC 210 "Quality management and corresponding general aspects for medical devices". Under the terms of the Vienna Agreement, a close collaboration with CEN/TC 243 should avoid duplication of standardization activities on similar subjects.	

6.4.9. ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

General Information			
Creation Date	**1994**	**Clinical laboratory testing and in vitro diagnostic test systems ISO/TC 212**	
Secretariat	ANSI (USA)		
Secretary	Mr. David Sterry		
Chairperson	Dr. Donald M. Powers		
Organizations in liaison	BIPM, EC4, EDMA, ELM, EUROM, ICSH, IFBLS, IFCC, ILAC, IUPAC, OECD, WASPaLM, WHO		
Subcommittees / Working groups	TC 212/WG 1 - Quality and competence in the medical laboratory TC 212/WG 2 - Reference systems TC 212/WG 3 - In vitro diagnostic products TC 212/WG 4 - Antimicrobial susceptibility testing		
Participating Members 	Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, China, Denmark, Finland, France, Germany, Islamic Republic of Iran, Ireland, Israel, Italy, Jamaica, Japan, Republic of Korea, Luxembourg, Malaysia, Netherlands, New Zealand, Portugal, Singapore, South Africa, Spain, Sweden, Turkey, USA, United Kingdom	**Observing Members** 	Bosnia and Herzegovina, Bulgaria, Croatia, Cuba, Cyprus, Czech Republic, Egypt, Estonia, Hong Kong/ China, Hungary, India, Malta, Mongolia, Norway, Romania, Russian Federation, Saudi Arabia, Switzerland, Thailand, Trinidad and Tobago, Uruguay, Zimbabwe
Total	31	**Total**	23
Participation of Luxembourg	Yes	**National delegates**	Mr. Dominique FERRAND ILNAS/OLAS Mrs. Marie-Estelle LARCHER Laboratoires Réunis Mrs. Marie-Laure FRIANT Laboratoire Ketterthill
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	14/09/2004
Scope	The scope of the ISO/TC 212 concerns the field of laboratory medicine and in vitro diagnostic test systems. This includes, for example, quality management, pre- and post-analytical procedures, analytical performance, laboratory safety, reference systems and quality assurance. The following fields, however, are excluded from the standardization activities of this technical committee: - generic quality management standards (dealt with by ISO / TC 176);

	- quality management standards for medical devices (dealt with by ISO / TC 210); - reference materials guidelines dealt with by the ISO Committee on Reference Materials (REMCO); - conformity assessment guidelines dealt with by the ISO Committee on Conformity assessment (CASCO).
Executive summary	The ISO/TC 212 addresses laboratory medicine through a focus on quality management, reference systems, in vitro diagnostic products, and antimicrobial susceptibility testing. The main fields range from laboratory measurement of quantities in samples of biological origin; testing the susceptibility of antimicrobial agents against bacteria involved in infectious disease; quality, competence, and safety in the laboratory; testing at the point-of-care; self-testing; and product labeling and validation.
Work Program	
Published standards	24
Standards under development	7
	➢ ISO/FDIS 15189: Medical laboratories - Requirements for quality and competence ➢ ISO/DIS 15197: In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus ➢ ISO/FDIS 16256: Clinical laboratory testing and in vitro diagnostic test systems - Reference method for testing the in vitro activity of antimicrobial agents against yeast of fungi involved in infectious diseases ➢ ISO/AWI 16782: Clinical laboratory testing - Criteria for acceptable lots of dehydrated Mueller-Hinton agar and broth for antimicrobial susceptibility testing ➢ ISO/AWI 17518: Medical Laboratories - Guidance for users of reagents for staining in biology in medical laboratories ➢ ISO/AWI 17822: Nucleic acid based in vitro diagnostics for detection and identification of microbial pathogens - General requirements and definitions ➢ ISO/DIS 19001: In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology
Comments	
The ISO/TC 212 works in liaison with other ISO technical committees: TC 48, TC 76, TC 150/SC 7, TC 176, TC 210, TC 215, Committee on conformity assessment (CASCO), Committee on reference materials (REMCO). It also collaborates with the IEC/TC 66 "Safety of measuring, control and laboratory equipment". In addition, ISO/TC 212 closely cooperates with CEN/TC 140 "In vitro diagnostics medical devices", thus following the terms of the Vienna Agreement.	

6.5. SUBSECTOR 5 – eHEALTH

eHealth is a recent term, dating back to at least 1999, and various definitions have been used over time to designate Information and Communication Technologies (ICT) applications in the health domain. Assuming the definition made by the Directorate-General for Health and Consumers (DG SANCO) of the European Commission, eHealth designates the tools and services using information and communication technologies in order to improve prevention, diagnosis, treatment, monitoring and management. Among others, it includes information and data sharing between patients, health service providers, hospitals and health professionals, electronic health records, telemedicine services, portable patient-monitoring devices, etc. Such tools and services are increasingly used and recognized as having a significant potential to improve the quality and productivity of healthcare systems. Given the pressures caused by an increasing ageing population and the need to improve the healthcare systems, these improvements and efficiencies will be of high importance.

Conscious of these issues, the European Commission created in December 2011 a network of national responsible authorities on eHealth in order to support the development of this sector[34].

Regarding the impact and contribution of standardization to this sector, several communications made by the EU Commission underlined the important role of standardization in achieving the objectives set out in the area of eHealth. This was the case in the communication in 2008 in the communication from the EU Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society[35].

In 2007 the European Commission addressed to the European Standards Organizations (CEN, CENELEC and ETSI) a mandate (M/403) on standardization in the field of eHealth. This mandate aims to provide a consistent set of standards to address the needs of this rapidly evolving field for the benefit of future healthcare provision.
Finally, the eHealth subsector was identified by the EU Commission, in the 2010-2013 ICT standardization work program[36], as a priority domain in terms of standardization actions.

The eHealth sector is also actively supported by the Government of Luxembourg as it is seen as a sustainable solution to improve the national healthcare system. In 2006, the national eHealth plan[37] was adopted to facilitate the exchange of the health data between health professionals through an interoperability platform and the *Agence eSanté*, a dedicated agency for eHealth services in Luxembourg.

For this subsector, 7 standardization technical committees were identified as interesting (3 at a European level and 4 at an international level).

[34] Commission implementing decision of December 22nd, 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth, link: http://ec.europa.eu/health/ehealth/docs/decision_ehealth_network_en.pdf
[35] Communication from the EU Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on telemedicine for the benefit of patients, healthcare systems and society, COM/2008/0689 final, link: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52008DC0689:EN:NOT
[36] "2010-2013 ICT Standardisation Work Programme for industrial innovation", European Commission, DG Enterprise & Industry, link: http://ec.europa.eu/enterprise/sectors/ict/files/ict-policies/2010-2013_ict_standardisation_work_programme_1st_update_en.pdf
[37] Plan d'action eSanté du Luxembourg, 2006: http://www.sante.public.lu/fr/systeme-sante/programme-esante/esante_plan_actions_detail_060704_060926.pdf

6.5.1. CEN/TC 251 Health informatics

General Information			
Creation Date	**1990**	**Health informatics CEN/TC 251**	
Secretariat	NEN (Netherlands)		
Secretary	Mrs. S. Golyardi		
Chairperson	Mr. R. Stegwee		
Organizations in liaison	COCIR, EC, GS1, HL7, Normapme		
Subcommittees / Working groups	CEN/TC 251/WG 1 - Information models CEN/TC 251/WG 2 - Terminology and knowledge representation CEN/TC 251/WG 3 - Security, safety and quality CEN/TC 251/WG 4 - Technology for interoperability		
Participating Members 	All the CEN's National Members: 27 European Union countries, Croatia, Former Yugoslav Republic of Macedonia, Turkey, Iceland, Norway and Switzerland	**Observing Members** 	-
Total	33	**Total**	-
Participation of Luxembourg	No	**National delegates**	No registered delegates
European Directives	**Directive 2007/47/EC** of the European Parliament of September 5th, 2007 amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC		
Standardization Mandates	**M/432:** Standardization mandate addressed to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices **M/433:** Standardization mandate addressed to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 93/42/EEC relating to medical devices, concerning graphical symbols for use in the labeling of medical devices containing phthalates		

Business Plan	
Version	24/06/2010
Scope	The CEN/TC 251 is carrying on standardization activities focusing on health informatics. The concept of health informatics is the application of the principles of information processing and the provision of solutions for information processing problems in the field of care. Health informatics include informatics applied to: biomedical, clinical, consumer and personal health, genetics, healthcare management, imaging, laboratory, medical devices, mental health, nursing, practice of professions allied to medicine, public and population health, research, social care, telecare, therapy, and veterinary domains.
Executive summary	The CEN/TC 251 in health informatics is a response to needs identified by the European Commission in terms of standardization. The health informatics sector is located at the intersection of two different worlds: information and computer science on one side and care professions and services on the other side. In addition, the sector is made up of a large number of software producers and is influenced by many national and regional governmental customers. This disparate EU global market requires a set of efficient standards.

Work Program	
Published standards	76
Standards under development	30
	➢ prEN ISO 11073-00000: Health informatics - Point-of-care medical device communication - Part 00000: Framework and overview ➢ prEN ISO 27789: Health informatics - Audit trails for electronic health records (ISO/DIS 27789:2011) ➢ prCEN/TR 15872: Health informatics - Guidance on patient identification and cross-referencing of identities ➢ FprEN ISO 11615: Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated medicinal product information (ISO/FDIS 11615:2012) ➢ FprEN ISO 11616: Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (ISO/FDIS 11616:2012) ➢ FprEN ISO 11238: Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on substances (ISO/FDIS 11238:2012) ➢ FprEN ISO 11239: Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging (ISO/FDIS 11239:2012) ➢ FprEN ISO 11240 : Health informatics - Identification of medicinal products - Data elements and structures for the unique identification and exchange of units of measurement (ISO/FDIS 11240:2012) ➢ FprEN ISO 1828: Health informatics - Categorial structure for classifications and coding systems of surgical procedures (ISO/FDIS 1828:2012) ➢ prEN ISO 21091: Health informatics - Directory services for healthcare providers, subjects of care and other entities (ISO/DIS 21091:2011) ➢ FprEN ISO 13119: Health informatics - Clinical knowledge resources - Metadata (ISO/DIS 13119:2011) ➢ prEN ISO 13120: Health informatics - Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClaML) (ISO/DIS 13120:2011) ➢ FprEN ISO 11073-10472: Health Informatics - Personal health device communication - Part 10472: Device specialization - Medication monitor (ISO/FDIS 11073-10472:2012) ➢ FprCEN ISO/TS 14265: Health Informatics - Classification of purposes for processing personal health information (ISO/TS 14265:2011) ➢ prEN ISO 18104 rev: Health informatics - Integration of a reference terminology model for nursing ➢ FprEN ISO 13940: Health informatics - System of concepts to support continuity of care ➢ prCEN ISO/TS 17251: Health Informatics - Business requirements for a syntax to exchange structured dose information for medicinal products ➢ prEN ISO 21549-1 rev: Health informatics - Patient healthcard data - Part 1: General structure ➢ FprEN ISO 13606-1: Health informatics - Electronic health record communication - Part 1: Reference model (ISO 13606-1:2008) ➢ prCEN ISO/TS 14441: Health Informatics: Security and privacy requirements for compliance testing of EHR systems ➢ FprEN ISO 11073-30400: Health informatics - Point-of-care medical device communication - Part 30400: Interface profile - Cabled Ethernet (ISO/FDIS 11073-

	30400:2012) ➢ FprEN ISO 11073-10420: Health informatics - Personal health device communication - Part 10420: Device specialization - Body composition analyzer (ISO/FDIS 11073-10420:2012) ➢ FprEN ISO 11073-10421: Health informatics - Personal health device communication - Part 10421: Device specialization - Peak expiratory flow monitor (peak flow) (ISO/FDIS 11073-10421:2012) ➢ prEN ISO 10781: Electronic health record-system functional model (ISO/DIS 10781:2012) ➢ prEN ISO 11073-10417 rev: Health informatics - Personal health device communication - Part 10417: Device specialization - Glucose meter ➢ FprEN ISO 11073-10406: Health informatics - Personal health device communication - Part 10406: Device specialization - Basic electrocardiograph (ECG) (1- to 3-lead ECG) (ISO/FDIS 11073-10406:2012) ➢ prEN ISO 11073-10418: Health informatics - Personal health device communication - Part 10418: Device specialization - International Normalized Ratio (INR) monitor ➢ prEN ISO 21549-2 rev: Health informatics - Patient healthcard data - Part 2: Common objects (ISO/DIS 21549-2:2012) ➢ prEN ISO 21549-3 rev: Health informatics - Patient healthcard data - Part 3: Limited clinical data (ISO/DIS 21549-3:2012) ➢ prEN ISO 21549-4 rev: Health informatics - Patient healthcard data - Part 4: Extended clinical data (ISO/DIS 21549-4:2012)

Comments

Under the Vienna agreement, CEN/TC 251 works in close collaboration with the ISO/TC 215 "Health informatics" which adopted many standards developed by the European technical committee.
CEN/TC 251 contributes actively in the CEN Advisory Board for Health Standards. Internationally, CEN/TC 251 participates to the Joint Initiative Council for Health Informatics Standards.

Much CEN/TC 251 work is therefore carried out in partnership with partner organizations such as Clinical Data Interchange Standards Consortium (CDISC), Digital imaging and communication in medicine (DICOM), Global Language for Business non-profit association (GS1), Health Level Seven International (HL7) and International Health Terminology Standards Development Organization (IHTSDO).

TC251 formed a European group of experts together with the medical device experts of CENELEC/TC62 under the banner, "Software as a medical device" (SAMD). The SAMD group has contributed to the EU guideline document "Qualification and classification of stand-alone software" published as MEDDEV 2.1/6 in January 2012. The MDD is currently being revised, so the SAMD group follows the developments and continues to provide its expert help in this area.

The first edition of the newsletter of the ISO/TC 251 on relevant news and activities was released in July 2012.

6.5.2. ETSI Project EP eHealth

General Information		
Creation Date	**2007**	**ETSI Project EP eHealth**
Chairperson	Mr. Saad Mezzour	
Organization Members	ETSI	
Website	http://www.etsi.org/WebSite/technologies/eHealth.aspx	
Scope	The EP eHealth of ETSI is an answer to the mandate M/403 made by the European Commission in the field of Information and Communication Technologies in health sector. ETSI Project EP eHEALTH coordinates ETSI's activities in the Information Communication Technology (ICT) applied in the health domain. Vital aspects to be considered by EP eHealth are Security of systems and data, Quality of services, Interoperability and validation by testing and Usability.	
Executive summary	One of the main goals of this project is to find interoperable solutions for healthcare data collection, transmission, storage and interchange, with appropriate security, privacy and reliability. To achieve this, experts developed a set of user service models for eHealth and service architecture and requirements to improve eHealth services, involving both users and medical professionals. To achieve these tasks an ETSI Specialist Task Force (STF 355) was created. Several reports were produced as a Technical Report (TR), which analyzed user services models, technologies and applications supporting eHealth. EP eHEALTH is working also in close collaboration with the other European Standards Organizations (CEN and CENELEC) in the joint project called "eHealth-INTEROP" (Cf. chapter 6.5.3).	
Structure	-	
Publications	The following standards have already been published: ➢ ETSI TR 102 764 V1.1.1 (2009-02): eHEALTH; Architecture; Analysis of user service models, technologies and applications supporting eHealth ➢ ETSI SR 002 564 V1.1.1 (2006-12): Applicability of existing ETSI and ETSI/3GPP deliverables to eHealth	
European Directives	**Directive 2007/47/EC** of the European Parliament of September 5th, 2007, amending Council Directive 90/385/EEC, 93/42/EEC and the Directive 98/8/EC	
Standardization Mandates	**Mandate M/403**: Mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies applied to the domain of eHealth.	
Comments	Participation in EP eHEALTH is open to all ETSI members in accordance with the Technical Working Procedures. Observers and non-members may participate at the discretion of the chairperson.	

6.5.3. CEN/CENELEC/ETSI Project eHealth-INTEROP

General Information		
Creation Date	**2008**	**eHealth – INTEROP CEN/CENELEC/ETSI Project**
Chairperson	Mr. Robert Stegwee	
Organization Members	CEN, CENELEC, ETSI	
Website	http://www.ehealth-interop.nen.nl/	
Scope	The "eHealth-INTEROP" project is a joint European initiative between CEN, CENELEC and ETSI. It addresses the requirements of the European Commission mandate (M/403) to the European Standards Organizations on standardization in the field of e-health. This European mandate aims to provide a consistent set of standards to address the needs of this rapidly evolving field for the benefit of future healthcare provision.	
Executive summary	The "eHealth-INTEROP" project was launched by the CEN, CENELEC and ETSI in 2008 following the request of the Commission to work on the implementation of the recommended eHealth interoperability process through a set of profiles to adopt from various eHealth projects across Europe. In March 2008, the Project Team was created through a selection of experts in order to prepare the draft report for Phase 1 of this project. The Project Team worked under the supervision of the eHealth-INTEROP Co-ordination Group and consists of the following persons: Melvin Reynolds (United Kingdom) as editor, Pantelis Angelidis (Greece), Charles Parisot (France) and Georg Heidenreich (Germany). In January 2009, a final version of the eHealth-INTEROP Report was approved by the three European Standardization Organizations and submitted to the European Commission for formal approval. The eHealth-INTEROP Report proposed to organize activities in support of five processes that should accelerate a European-wide coordinated interoperability standards adoption in health: - use case definition and prioritization, - standards development, - profile development and maintenance, - profile quality assurance test plans and tools, - sharing of best practices in deploying eHealth projects. The Netherlands Standardization Institute and the project team worked on the preparation of Phase 2 and on February 11th, 2009, a Workshop was organized for a number of major stakeholders to discuss the recommendations of the report to Phase 1 and to prepare a proposal for Phase 2 However, the EU Commission decision did not granted the project proposal mainly because current ehealth projects such as epSOS, Calliope, HITCH, EHR-QTN, NetC@rds, SemanticHealth, SmartPersonalHealth, STORK and ISA Study, include already goals and deliverables which were partly described in the proposal .	
Structure	The Project Team, composed of a group of experts, was in charge of preparing the draft report for Phase 1 of this project. The Project Team worked under the supervision of the eHealth-INTEROP Co-ordination Group composed by the three ESOs (CEN Secretariat and TC251 Chair, CENELEC Secretariat and TC62 Chair, ETSI Secretariat and eHealth Chair). In addition, the three ESOs established a collaborative mechanism in the form of a wider coordination group of EU and international standards bodies and consortia.	

Publications	eHealth-INTEROP Report in response to eHealth Interoperability Standards Mandate (SA/CEN/ENTR/000/2007-20 eHealth Mandate M/403 – Phase 1)
European Directives	**Directive 2007/47/EC** of the European Parliament and of the Council of September 5th, 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market
Standardization Mandates	**Mandate M/403**: Mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies applied in the domain of eHealth.

6.5.4. ISO/TC 215 Health informatics

General Information			
Creation Date	**1998**	**Health informatics ISO/TC 215**	
Secretariat	ANSI (USA)		
Secretary	Mrs. Lisa Spellman		
Chairperson	Mr. Christopher Chute		
Organizations in liaison	CDISC, COCIR, DICOM, EFPIA, GS1, HON, ICN, IHE, IHTSDO, IMIA, UNECE, WHO		
Subcommittees / Working groups	TC 215/WG 1 - Data structure TC 215/WG 2 - Data interchange TC 215/WG 3 - Semantic content TC 215/WG 4 - Security TC 215/WG 6 - Pharmacy and medicines business TC 215/WG 7 - Devices TC 215/WG 8 - Business requirements for Electronic Health Records TC 215/WG 9 - SDO Harmonization TC 215/CAG 1 - Executive council, harmonization and operations TC 215/JWG 7 - Joint ISO/TC 215 - IEC/SC 62A WG: Application of risk management to information technology (IT) networks incorporating medical devices		
Participating Members 	Armenia, Australia, Austria, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Finland, Germany, India, Islamic Republic of Iran, Ireland, Italy, Japan, Kenya, Republic of Korea, Luxembourg, Malaysia, Mexico, Netherlands, Norway, Philippines, Russian Federation, Singapore, Spain, Sweden, Switzerland, Tunisia, Turkey, USA, United Kingdom	**Observing Members** 	Argentina, Bulgaria, Colombia, Croatia, Cyprus, Ecuador, France, Hong Kong/China, Hungary, Israel, Kazakhstan, Mongolia, New Zealand, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, South Africa, Thailand, Ukraine, Zimbabwe
Total	33	**Total**	23
Participation of Luxembourg	Yes	**National delegates**	Mr. Michel ACKERMAN ebrc S.A.
European Directives	-		
Standardization Mandates	-		

Business Plan	
Version	04/11/2004
Scope	The ISO/TC 215 focuses its standardization activities in the field of information for health and ICT to promote interoperability between independent systems, to enable compatibility and consistency for health information and data, as well as to reduce duplication of effort and redundancies. The domain of ICT for health includes but is not limited to: - Healthcare delivery; - Disease prevention and wellness promotion; - Public health and surveillance; - Clinical research related to health services.
Executive summary	The main objective of ISO/TC 215 activities is to contribute to the improvement and maintenance of health by producing ISO standards, which the international community regards as necessary to enable the successful utilization of ICT in the health environment. Indeed, despite a large use of informatics in health care, the relative lack of robust standards in this area has been an important limiting factor to reach an optimal development.
Work Program	
Published standards	98
Standards under development	56
Comments	
A standard of interest published by this technical committee, and which can be mentioned, is the ISO/IEEE 11073 "Health informatics - Medical / health device communication standards" that establishes a standard definition of communication between medical, health care and wellness devices and with external computer systems. They provide automatic and detailed electronic data capture of client-related and vital signs information, and of device operational data. Following the requirements of the Vienna agreement, a close collaboration has been established between ISO/TC 215 and CEN/TC 251, as they both work on health informatics. In addition, this ISO technical committee is in liaison with many other ISO committees: JTC 1 and several of its subcommittees, TC 12, TC 37, TC 42, TC 46, TC 76, TC 84, TC 106, TC 121, TC 150, TC 154, TC 168, TC 170, TC 171, TC 172, TC 194, TC 198, TC 210, TC 212, TC 229, TC 249. Finally, cooperation is also active with the IEC/TC 62 "Electrical equipment in medical practice".	

6.5.5. ITU/ITU-T Study Group 16 e-health and standardization

General Information		
Creation Date	**2003**	**ITU-T Study Group 16 – e-health and standardization**
Chairperson	Mr. Yushi Naito	
Organization Members	Diverse experts coming from different sectors (government, industry, academics, other stakeholders)	
Website	http://www.itu.int/en/ITU-T/studygroups/com16/ehealth/Pages/default.aspx	
Scope	In the standardization activities of the ITU (ITU-T), the issues related to the e-health sector are handled by Question 28/16 (Multimedia framework for e-health applications). It focuses on standardization of Multimedia Systems to support e-health applications. This thematic was allocated to the ITU-T Study Group 16, which works on multimedia coding, terminals, systems and applications; one of its specific domains of action is the e-health sector.	
Executive summary	In May 2003, the ITU-T Study Group 16 "Multimedia services, systems and terminals" organized a Workshop on Standardization in E-health. Among the recommendations from the workshop was the creation of a study Question in SG 16 to address the needs of multimedia standardization for e-health applications. The study group dedicated to this question first worked on creating a roadmap of what standards exist and coordinated its planned actions with other organizations developing e-health standards. Other ITU Questions are related to subjects such as ITU-D SG 2 Question 14-2/2: Telecommunications for e-Health and ITU-T SG 17 Question 9/17: Telebiometrics.	
Structure	Study Group Structure of the ITU-T Study Group 16 is as follows: PLEN Plenary Q20/16 Multimedia coordination Q26/16 Accessibility to Multimedia Systems and Services WP 1/16 Network signal processing and voiceband terminals Q14/16 Voiceband modems and facsimile terminals protocols: specification, performance evaluation and interworking with NGN Q15/16 Voice gateway signal processing functions and circuit multiplication equipment / systems Q16/16 Speech enhancement functions in signal processing network equipment Q18/16 Interaction aspects of signal processing network equipment WP 2/16 Applications and systems Q1/16 Multimedia systems, terminals and data conferencing Q2/16 H.323 real-time multimedia system Q3/16 Multimedia gateway control architectures and protocols Q4/16 Advanced functions for H.300-series systems and beyond Q5/16 Telepresence systems Q12/16 Advanced multimedia system for NGN and other packet-based networks Q13/16 Multimedia application platforms and end systems for IPTV Q21/16 Multimedia architecture Q22/16 Multimedia applications and services Q24/16 Multimedia functions in NGN and other networks Q25/16 USN Applications and Services Q27/16 Vehicle gateway platform for telecommunication/ITS services/applications	

	Q28/16 **Multimedia framework for e-health applications** WP 3/16 Media coding Q6/16 Visual coding Q7/16 System and coordination aspects of media coding Q8/16 Generic sound activity detection Q9/16 [DELETED] Embedded variable bit rate coding of speech signals Q10/16 Speech and audio coding and related software tools
Publications	➢ ITU-T Technical Paper: Roadmap for Telemedicine (ITU-TFSTP-RTM) ➢ ITU-D Study Group 2: Mobile eHealth solutions for Developing Countries (Question 14-2, Final Report) ➢ E-health Standards and Interoperability (April 2012), by Dr. Laura DeNardis of American University in Washington, DC. ➢ Technology Watch Report Standards and E-health (January 2011), by Dr. Laura DeNardis of American University in Washington, DC.
Comments	Series of ITU-D e-Health Related mandates and resolutions are at the origin of the standardization activities of the ITU-T Study Group 16, such as: - ITU Hyderabad Action Plan Programme 2 (2010): Cybersecurity, ICT applications and IP-based network-related issues - ITU WTDC Resolution 65 (Hyderabad, 2010): Improving access to healthcare services by using information and communication technologies - ITU PP Resolution 183 (Guadalajara, 2010): Telecommunication/ICT applications for e-health - ITU WTDC Resolution 41 (Istanbul, 2002): e-Health including telehealth/telemedicine - ITU WTDC Resolution 54 (Doha, 2006): Information and communication technology applications

6.5.6. DICOM Digital imaging and communication in medicine

General Information		
Creation Date	**1983**	**DICOM – Digital imaging and communication in medicine**
Chairperson	Mr. Howard Clark	
Organization Members	National Electrical Manufacturers Association (NEMA) and The American College of Radiology (ACR)	
Website	http://medical.nema.org/	
Scope	DICOM (Digital Imaging and Communications in Medicine) Standards Committee was created to develop international standards for communication of biomedical diagnostic and therapeutic information in disciplines that use digital images and associated data. The goal of DICOM is to achieve compatibility and to improve workflow efficiency between imaging systems and other information systems in healthcare environments worldwide.	
Executive summary	The American College of Radiology (ACR) and the National Electrical Manufacturers Association (NEMA) formed a joint committee in order to create a standard method for the transmission of medical images and their associated information. They produced the DICOM Standards, a global Information Technology standard that enables the transfer of medical images in a multi-vendor environment and facilitates the development and expansion of picture archiving and communication systems.	
Structure	Activities on the standards are performed by the working groups of the DICOM Committee. These working groups are formed to work on particular subjects. The different DICOM Standards Working Groups are the following: • WG-01: Cardiac and Vascular Information • WG-02: Projection Radiography & Angiography • WG-03: Nuclear Medicine • WG-04: Compression • WG-05: Exchange Media • WG-06: Base Standard • WG-07: Radiotherapy • WG-08: Structured Reporting • WG-09: Ophthalmology • WG-10: Strategic Advisory • WG-11: Display Function Standard • WG-12: Ultrasound • WG-13: Visible Light • WG-14: Security • WG-15: Digital Mammography &CAD • WG-16: Magnetic Resonance • WG-17: 3D • WG-18: Clinical Trials & Education • WG-19: Dermatologic Standards • WG-20: Integration of Imaging &Information Systems • WG-21: Computed Tomography • WG-22: Dentistry • WG-23: Application Hosting • WG-24: Surgery • WG-25: Veterinary Medicine • WG-26: Pathology • WG-27: Web Technology for DICOM • WG-28: Physics	
Publications	➢ Third version of the DICOM standard - NEMA standard PS3 ➢ ISO standard 12052:2006 "Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management"	
Comments	Over 750 technical and medical experts participate in more than 20 active DICOM working groups. Close collaborations are set up with other organizations as through the joint DICOM/HL7 working group. The DICOM Standards Committee has also an active liaison to ISO/TC 215 "Health informatics".	

6.5.7. HL7 Health Level Seven International

General Information		
Creation Date	**1987**	**HL7 – Health Level Seven International**
Chairperson	Mr. Donald Mon	
Organization Members	Over 55 countries are affiliated to this organization	
Website	http://www.hl7.org/	
Scope	HL7 provides standards for interoperability that improve care delivery, optimize work-flow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including health-care providers, government agencies, the vendor community, fellow SDOs and patients.	
Executive summary	Health Level Seven International (HL7) is one of the American National Standards Institute (ANSI) and is an accredited Standards Developing Organizations (SDOs) operating in the healthcare sector. HL7 provides a framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated, set the language, structure the data types required. HL7 standards support clinical practices and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world.	
Structure	The HL7 standards are organized according to the following reference categories: Section 1: Primary Standards Section 2: Foundational Standards Section 3: Clinical and Administrative Domains Section 4: EHR Profiles Section 5: Implementation Guides Section 6: Rules and References Section 7: Education & Awareness	
Publications	Some of the standards developed by the HL7 have been approved by ISO: ➢ ISO/HL7 21731:2006: Health informatics - HL7 version 3 - Reference information model ➢ ISO/HL7 27932:2009: Data Exchange Standards - HL7 Clinical Document Architecture, Release 2 ➢ ISO/HL7 10781:2009: Electronic Health Record-System Functional Model ➢ ISO/HL7 27953-1:2011: Health informatics - Individual case safety reports (ICSRs) in pharmacovigilance - Part 1: Framework for adverse event reporting ➢ ISO/HL7 27951:2009: Health informatics - Common terminology services ➢ ISO/HL7 27953-2:2011: Health informatics - Individual case safety reports (ICSRs) in pharmacovigilance - Part 2: Human pharmaceutical reporting requirements for ICSR ➢ ISO/HL7 27931:2009: Data Exchange Standards - Health Level Seven Version 2.5 - An application protocol for electronic data exchange in healthcare environments ➢ ISO/TS 15000-2:2004: Electronic business eXtensible Markup Language (ebXML) - Part 2: Message service specification (ebMS) ➢ ISO/TS 11073-92001:2007: Health informatics - Medical waveform format - Part 92001: Encoding rules ➢ ISO 13606-3:2009: Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists ➢ ISO 21090:2011: Health informatics - Harmonized data types for information interchange	
Comments	Until now, 34 national HL7 exist and are affiliated with HL7 international. The HL7 Luxembourg was created in 2010 in order to coordinate the interests of the Luxembourg HL7 users, to maintain contacts to HL7 groups in other countries, scientific organizations and other actors in the area of health-care informatics, to work on the adaptation of HL7 standards to local needs, to contribute to international standards, etc. More information on HL7 Luxembourg is available here: http://www.hl7.lu/	

7. CONCLUSION

Europe is facing major challenges concerning the health sector with the ageing of its population: the necessity to find a balance between the provision of high-quality health services and the reduction of health costs. In parallel, this sector is seen by the EU Commission as a driver for growth, encouraging innovation and employing highly qualified workforce[38].

Therefore, the biomedical technologies constitute an innovative solution to correctly address these issues and improve the quality of the European healthcare systems. In Luxembourg, the Government has already launched major national initiatives in favor of the development of the biomedical technologies sector. While eHealth is seeking a sustainable solution to improve the healthcare system, international projects are also encouraged to develop national expertise in the field of molecular medicine.

Under this context, standardization activities constitute a key element to strengthen the implementation of the national health strategy and the development of the biomedical technologies sector in Luxembourg.

Based on the national standardization strategy initiated by ILNAS, this standards analysis has as main objectives to, primarily, inform the national stakeholders of the biomedical technologies sector of the standards developments and, secondly, to raise their awareness of the potential benefits that they could obtain in following and participating in standardization.

This standards analysis is based on a standards watch that identified technical committees potentially interesting to the national stakeholders. In parallel, to convince them of the interest to take part to standardization activities, their potential interests according the different subsectors of the biomedical technologies are detailed and opportunities for the market are proposed.

However, more than a simple presentation of a standardization panorama of the biomedical technologies sector, this standards analysis should be seen as a starting point for further discussions and involvement. As stated, the main aim of this analysis is to raise awareness of the national stakeholders of the biomedical technologies for participating in standardization and to perceive this issue as interesting and efficient economic leverage. As participation in standardization is a voluntary process, a clear understanding of these concerns by the national stakeholders is of primary importance in order to master the challenges linked with standardization in the biomedical technologies sector and to engage an individual process to participate.

ILNAS, supported by ANEC, will provide an active contribution and support future national delegates by offering training and information. As already done for the ICT and Energy sectors, following the presentation of this standards analysis, each stakeholder category would be invited to give their comments on the analysis results and proposed opportunities. A consultative committee would be created for this occasion in order to validate some of the proposals and to confirm the interest of the national market for the creation of a Standardization Forum dedicated to the biomedical technologies sector.

[38] European Commission, Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020, 2011 [COM/2011/709]: http://ec.europa.eu/health/programme/docs/prop_prog2014_en.pdf

8. APPENDIX

8.1. ACRONYM LIST

ACRONYM	TITLE
ABHS	CEN-CENELEC Advisory Board for Healthcare Standards
AG	Advisory Group
AHG	Ad hoc Group
AHWP	Asian Harmonization Working Party
AIII	Association of International Industrial Irradiation
ANEC	*Agence pour la normalisation et l'économie de la connaissance*
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BIPM	International Bureau of Weights and Measures
BT	Technical Board
CDISC	Clinical Data Interchange Standards Consortium
CEN	European Committee for Standardization
CENELEC	European Committee for Electrotechnical Standardization
CHeF	CEN Healthcare Forum
CI	Consumers International
CICR	International Committee of the Red Cross
CLSI	Clinical and Laboratory Standards Institute
COCIR	European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
COWS	Commission on World Standards of the World Association of Societies of (Anatomic and Clinical) Pathology
CWA	CEN Workshop Agreement
DFID	Department for International Development
DICOM	Digital Imaging and Communications in Medicine
DITTA	International Congress of Diagnostic Imaging and Therapy Systems Trade Associations
DS	Danish Standards Foundation
DSM	Standards Malaysia
EC	European Commission
EC4	European Communities Confederation of Clinical Chemistry
EDANA	European Disposables and Nonwovens Association
EDMA	European Diagnostics Manufacturers Association
EEC	European Economic Community
EFO	European Federation of Osteopaths
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association

ACRONYM	TITLE
EIG	Economic Interest Grouping
EIGA	European Industrial Gases Association
ELM	European Laboratory Medicine
ENTSO-E	European Network of Transmission System Operators for Electricity
EQALM	European Committee for External Quality Assurance Programmes in Laboratory Medicine
EREC	European Renewable Energy Council
ESO	European Standardization Organization
ETSI	European Telecommunications Standards Institute
EU	European Union
EUCOMED	European Medical Technology Industry Association
EUROM VI	European Federation of Precision Mechanical and Optical Industries
FIDE	Federation of the European Dental Industry
FMAC	World Veterans Federation
FORE	Forum for Osteopathic Regulation in Europe
GDP	Gross Domestic Product
GHTF	Global Harmonization Task Force
GS1	Global Language for Business non-profit association
HON	Health On the Net Foundation
IAEA	International Atomic Energy Agency
ICG	International Commission on Glass
ICN	International Council of Nurses
ICS	International Classification for Standards
ICSH	International Committee for Standardization in Haematology
ICT	Information and Communication Technologies
IEA	International Energy Agency
IEC	International Electrotechnical Commission
IFBLS	International Federation of Biomedical Laboratory Science
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IFRC	International Federation of Red Cross and Red Crescent Societies
IHE	Integrating the Healthcare Enterprise
IHTSDO	International Health Terminology Standards Development Organization
ILAC	International Laboratory Accreditation Cooperation
ILNAS	*Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services*
IMIA	International Medical Informatics Association
IPPF	International Planned Parenthood Federation
ISO	International Organization for Standardization
ISPO	International Society for Prosthetics and Orthotics
ISTH	International Society of Thrombosis & Haemostasis

ACRONYM	TITLE
ITU	International Telecommunication Union
IUPAC	International Union of Pure and Applied Chemistry
IVD	In Vitro Diagnostic
JTC	Joint Technical Committee
JWG	Joint Working Group
MT	Maintenance Team
NGO	Non-Governmental Organization
OECD	Organization for Economic Co-operation and Development
OIML	International Organization of Legal Metrology
OLN	*Organisme Luxembourgeois de Normalisation*
PATH	Program for Appropriate Technology in Health
PT	Project Team
RI	Rehabilitation International
RTTE	Radio and Telecommunications Terminal Equipment
SB	Standards Body
SBA	Sterile Barrier Association
SC	Subcommittee
SCC	Standards Council of Canada
SFEM	Sector Forum on Energy Management
SG	Strategic Group
SIS	Swedish Institute of Assistive Technology
TC	Technical Committee
UNCTAD	United nations conference on trade and development
UNEP	United Nations Environment Programme
UNFPA	United Nations Population Fund
UNIDO	United nations industrial development organization
WASP	World Association of Societies of (Anatomic and Clinical) Pathology
WASPaLM	World Association of Societies of Pathology and Laboratory Medicine
WBU	World Blind Union
WCO	World Customs Organization
WEC	World Energy Council
WEF	World Economic Forum
WFSA	World Federation of Societies of Anesthesiologists
WG	Working Group
WHO	World Health Organization
WMO	World Meteorological Organization

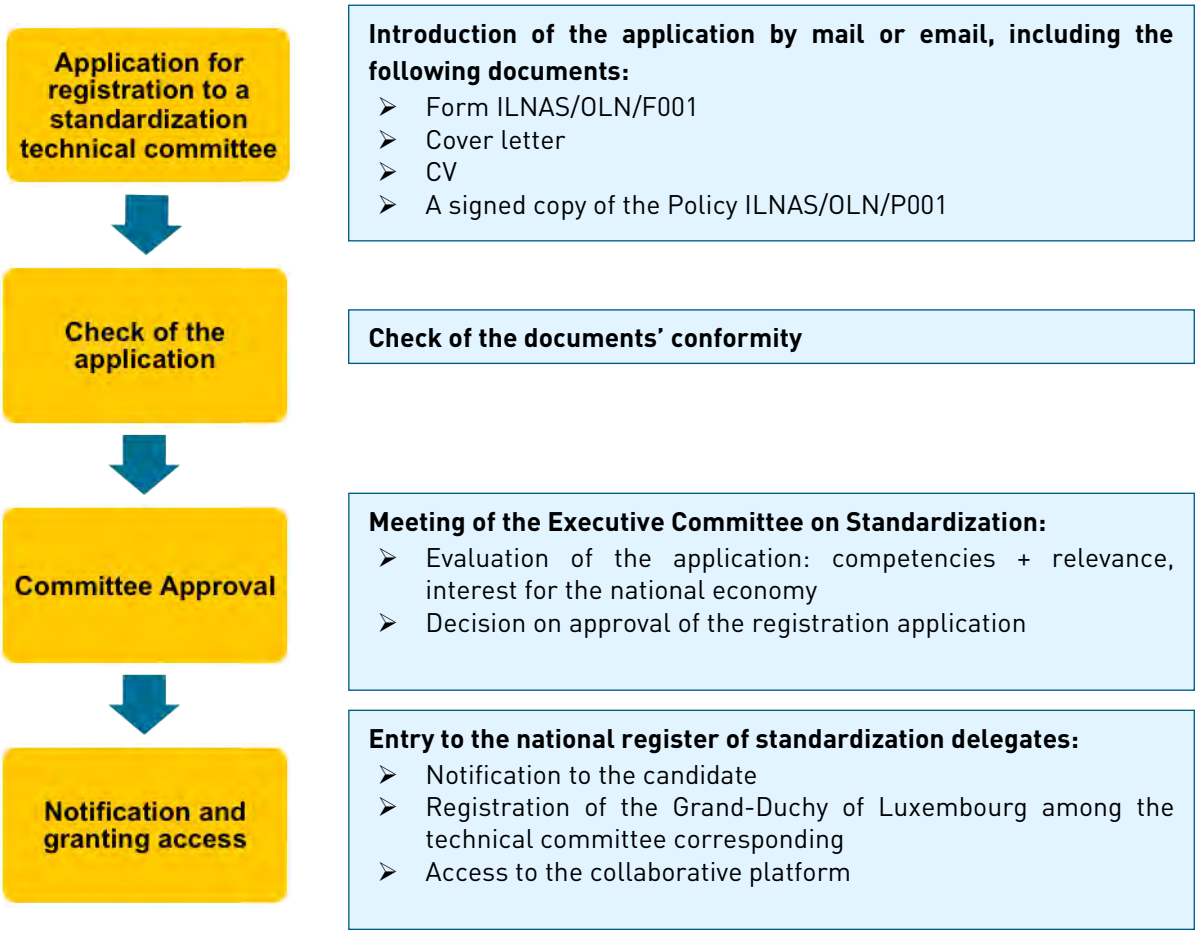
8.2. PARTICIPATION IN STANDARDIZATION PROCESS

To participate in standardization activities at the national, European or international level, each interested person has to become registered within Luxembourg's national standards body, ILNAS. A specific department, the "*Organisme Luxembourgeois de Normalisation*" (OLN), fulfills the ILNAS missions as a national standardization organization.
Indeed, in the framework of the standardization process, a national standards body recognized at national level is eligible to be a national member of the corresponding international and European standards organizations. In addition, the OLN can surround itself with experts from administrations, public services, professional organizations, groups, associations or institutions interested in standardization, as well as all persons or legal entities interested in participating in standardization.
In order to give access to standardization processes to all national socio-economic stakeholders, the registration as national delegate is entirely free of charge in Luxembourg.
To propose a framework for the standardization work of the national delegates and their participation in standardization technical committees, ILNAS has released a policy giving the main guidelines to the delegates regarding standardization processes and activities. This document, entitled "*Politique relative à la participation dans les comités techniques de normalisation*" is referenced as ILNAS/OLN/P001.

❖ Registration process to a standardization technical committee

Figure 8 (below) summarizes the process for registering as a national delegate to a standardization technical committee.

Figure 8: Registration process to a standardization technical committee



Detailed information on the registration process is available through the following internet link: http://www.ilnas.public.lu/fr/normes-normalisation/participation-aux-travaux-de-normalisation/comites-techniques.

The OLN represents Luxembourg's interests in the European standardization organizations as CEN, CENELEC and ETSI, as well as the international standardization organizations ISO and the IEC. Thus, each delegate has to specify the name of the European/international technical committee, but also sub-committee and working group, on which he or she wants to participate.

❖ National register of standardization delegates registered for standardization technical committees

The national register of the standardization delegates participating in standardization technical committees is updated regularly. This register can be accessed through the following internet link: http://www.ilnas.public.lu/fr/normes-normalisation/participation-aux-travaux-de-normalisation/comites-techniques.

❖ Rights and duties of a national delegate in standardization

According the actual version of the Policy (ILNAS/OLN/P001 - version 3), national delegates in standardization have the right to:

- access any documents of the technical committee through a collaborative platform;
- work on standards under development of a technical committee;
- take a position during the validation or approval process;
- participate in European and/or international meetings;
- give feedback to the OLN, if necessary, on malfunctions;
- use the logo "Member of ILNAS Network" in technical contributions.

In return, national delegates have to respect some duties, such as:

- the respect of the standardization policy of the OLN and the terms and conditions of use of the logo "Member of the ILNAS Network"(ILNAS/OLN/A003);
- the commitment of nondisclosure of the technical committee's documents to third parties;
- active participation in the standardization process is required when registered to a national standardization study committee;
- providing a periodic review to the OLN (personal activities, active participation, commentaries, etc.).

In conclusion, if you have skills and experience in the field of biomedical technologies or if you want to anticipate future requirements and influence the market, then do not hesitate to join the standardization process. A simple registration form has to be completed and introduced with the required documents (CV, cover letter, a signed copy of the politics). After the approval of your application, ILNAS will grant you full access to standardization works and you will become a full member of the standards network.

ILNAS, supported by ANEC, provides active support to new delegates in order to give them all the necessary information to efficiently participate in the standardization process.

8.3. LIST OF EU STANDARDIZATION MANDATES

This list of EU standardization mandates was extracted from the database dedicated to the European mandates[39] – Extraction date: June 27th, 2012.

Ref.	Mandate title	Object	Related Directives	Transmission date to EU standardization bodies
M/252	Mandate to CEN and CENELEC concerning the development of European standards relating to in vitro diagnostic medical devices	Vitro diagnostic medical devices	Council directive 93/42/EEC Council directive 98/79/EC	12/09/1997
M/295	Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices	Medical devices	Council directive 93/42/EEC Council directive 90/385/EEC	09/09/1999
M/320	Mandate to CEN concerning the development of European standards relating to medical devices	Medical devices / breast implants	Council directive 93/42/EEC Council directive 90/385/EEC Council directive 98/79/EC	13/06/2002
M/321	Mandate to CEN and CENELEC concerning the development of European standards relating to medical devices	Medical devices	Council directive 93/42/EEC Council directive 90/385/EEC Council directive 98/79/EC	13/06/2002
M/322	Mandate to CEN, CENELEC and ETSI for the alignment of medical devices standards to the Radio and Telecommunications Terminal Equipment (RTTE) Directive	Medical devices / RTTE Directive	Council directive 93/42/EEC Council directive 90/385/EEC	20/08/2002
M/332	Mandate to CEN/ CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of en 1970: 2000 "beds for the disabled"	Electrical safety / Beds for the disabled	Council directive 93/42/EEC	07/07/2003
M/333	Mandate to CEN concerning flammability of mattresses and bed bases for medical purposes	Flammability of mattresses and bed bases	Council directive 93/42/EEC	23/10/2003

[39] http://ec.europa.eu/enterprise/standards_policy/mandates/database/

Ref.	Mandate title	Object	Related Directives	Transmission date to EU standardization bodies
M/342	Mandate to CEN/CENELEC concerning the development of European standards relating to medical devices	Medical devices / hyperbaric chambers for medical purposes	Council directive 93/42/EEC	10/02/2004
M/384	Mandate to CEN concerning the development of European standards relating to colour systems intended for specimens receptacles used for in vitro diagnostic medical devices	Colour systems intended for specimens receptacles in IVDM	Council directive 98/79/EC	06/04/2004
M/403	Mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies	eHealth	Directive 2007/47/EC	06/03/2007
M/432	Mandate addressed to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 90/385/EEC and Directive 93/42/EEC relating to medical devices	Medical devices	Council directive 93/42/EEC Council directive 90/385/EEC Directive 2007/47/EC	24/11/2008
M/433	Mandate addressed to CEN and CENELEC within the framework of Directive 2007/47/EC amending Directive 93/42/EEC relating to medical devices, concerning graphical symbols for use in the labeling of medical devices containing phthalates	Labeling of medical devices containing phthalate	Council directive 93/42/EEC Directive 2007/47/EC	24/11/2008
M/467	Mandate addressed to CEN and CENELEC: modification and completion of EN 60601-2-52 to prevent entrapment of children and of adults with an atypical anatomy in medical beds and entrapment of children in medical cots	Medical beds and entrapment of children in medical cots	Council directive 93/42/EEC	19/05/2010

8.4. LIST OF ALL IDENTIFIED STANDARDIZATION TECHNICAL COMMITTEES

The standards watch of the biomedical technologies sector has identified 121 standardization technical committees (European and International), which are presented in the following table.
In **bold** and between brackets (), the number of national delegates registered in the national register of standardization delegates (version 50 of July 3rd, 2012) managed by ILNAS. In red, most active technical committees in terms of current, dynamic and strategic (42 in total).

SUBSECTOR	ORIGINE	TECHNICAL COMMITTEE (TC)
MEDICAL DEVICES	CEN	CEN/TC 23 Transportable gas cylinders
		CEN/TC 55 Dentistry
		CEN/TC 69 Industrial valves
		CEN/TC 138 Non-destructive testing
		CEN/TC 205 Non-active medical devices
		CEN/TC 248 Textiles and textile products
		CEN/TC 258 Clinical investigation of medical devices
		CEN/TC 261 Packaging **(1 national delegate)**
		CEN/TC 285 Non-active surgical implants
		CEN/TC 316 Medical devices utilizing tissues
		CEN/SS S02 Transfusion equipment
		CEN/SS S03 Syringes
	CEN/CLC	CEN/CLC/JWG/AIMD CEN/CENELEC Joint Working Group on Active Implantable Medical Devices
	ISO	ISO/TC 58/SC 2 Cylinder fittings **(1 national delegate)**
		ISO/TC 58/SC 4 Operational requirements for gas cylinders
		ISO/TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use **(1 national delegate)**
		ISO/TC 84 Devices for administration of medicinal products and intravascular catheters **(1 national delegate)**
		ISO/TC 94/SC 13 Protective clothing
		ISO/TC 106 Dentistry
		ISO/TC 110/SC 3 Castors and wheels
		ISO/TC 122 Packaging **(2 national delegates)**
		ISO/TC 150 Implants for surgery
		ISO/TC 157 Non-systemic contraceptives and STI barrier prophylactics
		ISO/TC 159 Ergonomics
		ISO/TC 168 Prosthetics and orthotics
		ISO/TC 170 Surgical instruments
		ISO/TC 210 Quality management and corresponding general aspects for medical devices **(1 national delegate)**

SUBSECTOR	ORIGINE	TECHNICAL COMMITTEE (TC)
MEDICAL EQUIPMENT	CEN	CEN/TC 10 Lifts, escalators and moving walks **(1 national delegate)**
		CEN/TC 79 Respiratory protective devices
		CEN/TC 102 Sterilizers for medical purposes **(1national delegate)**
		CEN/TC 122 Ergonomics
		CEN/TC 123 Lasers and photonics
		CEN/TC 170 Ophthalmic optics
		CEN/TC 204 Sterilization of medical devices
		CEN/TC 215 Respiratory and anesthetic equipment **(1 national delegate)**
		CEN/TC 239 Rescue systems
		CEN/TC 293 Technical aids for disabled persons
		CEN/TC 332 Laboratory equipment **(1 national delegate)**
		CEN/TC 359 Project Committee - Hyperbaric chambers
		CEN/SS S99 Health, environment and medical equipment - Undetermined
	CLC	CENELEC/TC 61 Safety of household and similar electrical appliances
		CENELEC/TC 62 Electrical equipment in medical practice
		CENELEC/TC 76 Optical radiation safety and laser equipment
		CENELEC/TC 106X Electromagnetic fields in the human environment
		CENELEC/SR 87 Ultrasonics
	CEN/CLC	CEN/CLC/TC 3 Quality Management and corresponding general aspects of medical devices
	IEC	IEC/TC 62 Electrical equipment in medical practice
		IEC/SC 62A Common aspects of electrical equipment used in medical practice
		IEC/SC 62B Diagnostic imaging equipment
		IEC/SC 62C Equipment for radiotherapy, nuclear medicine and radiation dosimetry
		IEC/SC 62D Electromedical equipment
		IEC/TC 64 Electrical installations and protection against electric shock
		IEC/TC/SC 76 Optical radiation safety and laser equipment
		IEC/TC/SC 87 Ultrasonics
	ISO	ISO/TC 42 Photography
		ISO/TC 43 Acoustics **(1 national delegate)**
		ISO/TC 45 Rubber and rubber products
		ISO/TC 48 Laboratory equipment
		ISO/TC 85 Nuclear energy, nuclear technologies, and radiological protection
		ISO/TC 85/SC 2 Radiological protection
		ISO/TC 121 Anesthetic and respiratory equipment **(1 national delegate)**
		ISO/TC 135/SC 5 Radiation methods
		ISO/TC 172 Optics and photonics
		ISO/TC 173 Assistive products for persons with disability
		ISO/TC 178 Lifts, escalators and moving walks
		ISO/TC 198 Sterilization of health care products **(1 national delegate)**

SUBSECTOR	ORIGINE	TECHNICAL COMMITTEE (TC)
MEDICAL SERVICES	CEN	CEN/WS 068 Health care services – Basic quality criteria for health checks Quality criteria for health checks
		CEN/TC 192 Fire service equipment **(1 national delegate)**
		CEN/TC 362 Project Committee - Healthcare services - Quality management systems
		CEN/TC 394 Project Committee - Services of chiropractors
		CEN/TC 403 Project Committee - Aesthetic surgery services
		CEN/TC 414 Project Committee - Services of osteopaths
	CEN/CLC	CEN/CLC/TC 1 Criteria for conformity assessment bodies
	ISO	ISO/TMB Technical Management Board
		ISO/TC 223 Societal security
DIAGNOSTICS	CEN	CEN/WS 055 Guidance Document for CWA 15793:2008 Laboratory Biorisk Management Standard
		CEN/TC 140 In vitro diagnostic medical devices
		CEN/TC 206 Biocompatibility of medical and dental materials and devices
		CEN/TC 216 Chemical disinfectants and antiseptics
		CEN/TC 243 Cleanroom technology
		CEN/TC 264 Air quality **(4 national delegates)**
		CEN/TC 347 Methods for analysis of allergens
		CEN/TC 367 Project Committee - Breath-alcohol testers
		CEN/TC 416 Project Committee - Health risk assessment of chemicals
	CLC	CENELEC/BTTF 116-2 Alcohol interlocks
		CENELEC/SR 66 Safety of measuring, control, and laboratory equipment
	IEC	IEC/TC 66 Safety of measuring, control and laboratory equipment
	ISO	ISO/TC 194 Biological evaluation of medical devices
		ISO/TC 209 Cleanrooms and associated controlled environments
		ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems **(3 national delegates)**
	ISO/IEC	ISO/IEC/CASCO Committee on conformity assessment
EHEALTH	CEN	CEN/TC 251 Health informatics
	ISO	ISO/TC 215 Health informatics **(1 national delegates)**
	ISO/IEC	ISO/IEC/JTC 1 Information technology
		ISO/IEC/JTC 1/SC 28 Office equipment
		ISO/IEC/JTC 1/SC 35 User interfaces
		ISO/IEC JTC 1/SC 37 Biometrics
	ETSI	ETSI/eHEALTH ETSI Project eHEALTH
	CEN/CLC/ ETSI	CEN / CENELC /ETSI Joint Project eHealth-INTEROP
	OTHERS	HL7 Health Level Seven International
		ITU/ITU-T Study Group 16 ITU-T Study Group 16: e-health and standardization
		NEMA - National Electrical Manufacturers Association/DICOM Digital imaging and communication in medicine

SUBSECTOR	ORIGINE	TECHNICAL COMMITTEE (TC)
NO SUBSECTOR IDENTIFIED	CEN	CEN/TC 126 Acoustic properties of building elements and of buildings
		CEN/SS I44 Nanotechnologies
		CEN/TC 178 Paving units and kerbs **(1 national delegate)**
		CEN/TC 315 Spectator facilities
		CEN/TC 352 Nanotechnologies
		CEN/TC 392 Cosmetics
		CEN Advisory Board for Healthcare Standards (ABHS)
	CLC	CENELEC/TC 59X Performance of household and similar electrical appliances
		CENELEC/TC 79 Alarm systems
	ETSI	ETSI/ERM Electromagnetic Compatibility and Radio Spectrum Matters
		ETSI/SAFETY
	IEC	IEC/TC/SC 1 Terminology
		IEC/TC/SC 59 Performance of household and similar electrical appliances
		IEC/TC/SC 61 Safety of household and similar electrical appliances
	ISO	ISO/TC 217 Cosmetics
		ISO/TC 229 Nanotechnologies
		ISO/TC 230 Project Committee: Psychological assessment
		ISO/TC 249 Traditional Chinese medicine
		ISO/TC 266 Biomimetics

8.5. CONTACTS

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