A019

Legislation concerning notification of conformity assessment bodies

Modifications: complete revision of the document

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Contents

1. Purpose

The purpose of this document is to present the « New Approach » directives and regulations for which OLAS accredits conformity assessment bodies (CAB) in the context of their notification to European Commission and EU Member States.

The new requirements that will apply to notified bodies following alignment of the directives with the decision n° 768/2008/EC are presented in a general way in chapter 3 of the present document.

Chapter 4 aims to indicate, for each directive, the national transposition and modules for which the CABs notified by OLAS, to the European Commission and EU Member States, are accredited. The "requirements relating to notified bodies" are also presented there. The document *EA-2/17 INF - EA Document on Accreditation for Notification Purposes* provides a link between these requirements and the different accreditation standards. Thus, if a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards (or parts thereof), it is presumed to comply with the "requirements relating to notified bodies" in so far as the applicable harmonised standards cover those requirements.

2. Introduction

The « New Approach » directives include about thirty directives that define the essential requirements that products have to fulfill for their CE marking, which is their passport to the internal market of the EU.

About 1700 « notified bodies » have been designated by the Member States to provide assessment services in order to guarantee the conformity of products with respect to the european regulations. All these organisms are listed in the NANDO (New Approach Notified and Designated Organisations) database.

Since 1st June 2008, accreditation is mandatory in Luxembourg for conformity assessment activities for which a CAB wants to be notified to the European Commission and the other Member States. The OLAS procedure *P008 – Designation of notified bodies within the framework of the « New Approach » Directives* lays down the rules to getting, maintaining or modifying its notification.

Conformity assessment procedures

The decision n° 90/683/EEC foresaw eight assessment procedures (« modules »), that apply to the conception and/or production phases:

- internal production control (module A) ;
- EC type-examination (module B) ;
- conformity to type (module C) ;
- production quality assurance (module D) ;
- product quality assurance (module E) ;
- product verification (module F) ;
- unit verification (module G) ;
- full quality assurance (module H).

The CE marking of a product is affixed following the declaration of conformity of the manufacturer. Depending on the module, intervention of a notified conformity assessment body is required or not.

In 1993, decision n° 93/465/EEC has repealed decision n° 90/683/CEE and redefined a first time these modules. Finally, decision n° 768/2008/EC repealed decision n° 93/465/CEE and brought further modification to the different modules.

Regulation (EU) n° 305/2011 concerning construction products is a special case. While reference provisions of the decision n° 768/2008/EC have been included in the regulation, it does not use the conformity assessment modules, but it describes 5 systems of assessment and verification of constancy of performances:

- systems 1+/1 : certification of the constancy of performances by a notified body;
- system 2+ : certification of factory production control by a notified body;
- system 3 : determination of the product-type by a notified laboratory;
- system 4 : declaration by the manufacturer.

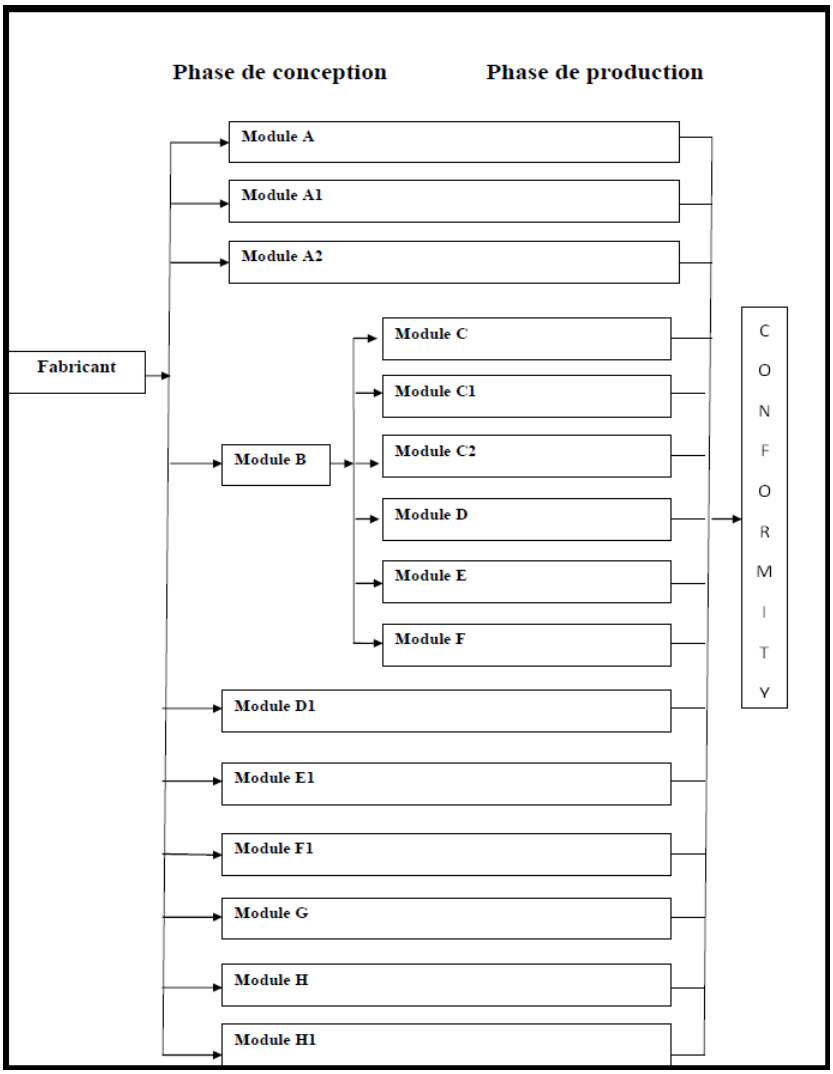
3. Decision n° 768/2008/EC

Decision n° 768/2008/EC includes reference provisions that have to be integrated into the legislation relating to products, but it has no direct legal effect. As « New Approach » directives are aligned with this decision, and following transposing into national legislation, the new requirements become mandatory. In all directives, the applicable conformity assessment (modules) will be taken from the decision, while specifying that some differences might be kept because of the specificities of one sector or another.

As products are subjected to conformity assessment both during the design and production phase, a conformity assessment procedure covers both design and production phases.

A module may cover:

- either one of these two phases (in this case a conformity assessment procedure is composed of two modules);
- or both phases (in this case a conformity assessment procedure is composed of one module).



Source: Blue Guide 2014

3.1. New requirements for notified bodies

Following alignment of the directives with decision n°768/2008/EC, some new requirements applicable to notified bodies will be introduced into the legislation concerning products that are placed on the European market:

- Requirements regarding impartiality and independence are extended to activities of subsidiaries and subcontractors of notified bodies. It is also added that a notified body shall not be the purchaser, owner, user or maintainer of the products which they assess.
- Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Notified bodies shall have procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.
- Conformity assessment bodies shall participate in relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation.
- Notified bodies shall inform the notifying authority any refusal, restriction, suspension or withdrawal of a certificate, as well as any request for information which they have received from market surveillance authorities regarding conformity assessment activities.

3.2. Developments in conformity assessment procedures (modules)

Modifications introduced at the level of the modules by decision n° 768/2008/EC include:

- The possibility for the manufacturer to use an accredited in-house body (instead of an notified body) for the tests carried out in the framework of modules A1, A2, C1 et C2.
- The possibility for the legislator to limit the EC-type examination to examining only the technical documentation and/or critical parts of the specimen (rather than the complete product).
- The possibility of using modules D, E and F not in combination with module B, but on their own was already given in the footnotes to old modules D, E and F. Those options now become modules D1, E1 and F1.
- Module H1 supersede the supplementary option « design examination » that figures in old module H.
- In the context of the new modules B, H and H1, the notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument.
- For quality system assessments, it has been specified that the auditing team shall have knowledge of the applicable requirements of the legislative instrument.

The document CERTIF doc. 2008-002, drawn up by the European Commission, includes a detailed analysis of the differences between the old and new modules.

3.3. Summary of the modules according to the decision n° 768/2008/EC:

Conception

A. Internal production control Manufacturer - keeps technical documentation at the disposal of national authorities.	**B. Type examination** Manufacturer submits to notified body: - technical documentation, - supporting evidence for the adequacy of the technical design solution, - specimen(s), representative of the production envisaged, as required. Notified body: - ascertains conformity with essential requirements, - examines technical documentation and supporting evidence to assess adequacy of the technical design, - for specimen(s): carries out tests, if necessary, - issues EC-type examination certificate.				**G. Unit verification** Manufacturer: - submits technical documentation.	**H. Full quality assurance** *EN ISO 9001:2000*[4] Manufacturer: - operates an approved quality system for design, - submits technical documentation. Notified body: - carries out surveillance of the QS. **H1.** Notified body: - verifies conformity of design [1], - issues EC-design examination certificate [1].
A. Manufacturer: Declares conformity with essential requirements, - affixes required conformity marking. **A1.** Accredited in-house body or notified body - tests on specific aspects of the product [1] **A2.** Product checks at random intervals [1].	**C. Conformity to type** Manufacturer: - declares conformity with approved type, - affixes required conformity marking. **C1.** Accredited in-house body or notified body - tests on specific aspects of the product [1] **C2.** Product checks at random intervals [1].	**D. Production quality assurance** *EN ISO 9001:2000*[2] Manufacturer: - operates an approved quality system for production, final inspection and testing, - declares conformity with approved type, - affixes required conformity marking. **D1.** declares conformity to essential requirements - affixes required conformity marking Notified body: - approves the QS, - carries out surveillance of the QS.	**E. Product quality assurance** *EN ISO 9001:2000*[3] Manufacturer: - operates an approved quality system for final inspection and testing, - declares conformity with approved type, - affixes required conformity marking. **E1.** declares conformity to essential requirements - affixes required conformity marking Notified body: - approves the QS, - carries out surveillance of the QS.	**F. Product verification** Manufacturer: - declares conformity with approved type, - affixes required conformity marking. **F1.** declares conformity to essential requirements - affixes required conformity marking Notified body: - verifies conformity to essential requirements, - issues certificate of conformity.	Manufacturer: - submits product, - declares conformity, - affixes required conformity marking. Notified body: - verifies conformity to essential requirements, - issues certificate of conformity.	Manufacturer: - operates an approved QS for production, final inspection and testing, - declares conformity, - affixes required conformity marking. Notified body: - carries out surveillance of the QS.

Production

[1] Supplementary requirements which may be used in sectoral legislation.
[2] Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
[3] Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.
[4] Except for requirements relating to customer satisfaction and continual improvement.

4. Presentation of "New approach" directives and regulations for which OLAS accredits conformity assessment bodies.

4.1. Pyrotechnic articles

National transposition: Loi du 27 mai 2016 concernant la mise à disposition sur le marché d'articles pyrotechniques

Luxembourg notified body: SNCH (modules B, C2, D, E, G)

Module A. Internal production control	Module B. Type examination				Module G. Unit verification	Module H. Full quality assurance
	Module C2. Conformity to type	Module D. Production quality assurance	Module E. Product quality assurance	Module F. Product verification		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 2007/23/EC	Directive 2013/29/UE *Applicable from 1st July 2015.*
Conformity assessment procedures	
Module B EC type-examination	**Annex II Module B** EU-type examination
Module C Conformity to type	**Annex II Module C2** Conformity to type based on internal production control plus supervised product checks at random intervals
Module D Production quality assurance	**Annex II Module D** Conformity to type based on quality assurance of the production process
Module E Product quality assurance	**Annex II Module E** Conformity to type based on product quality assurance
Module G Unit verification	**Annex II Module G** Conformity based on unit verification
Module H Full quality assurance	**Annex II Module H** Conformity based on full quality assurance
Requirements relating to notified bodies	
Annex III	**Article 25**
>>> see analysis in the annex of the present document <<<	
Operational obligations of notified bodies	
/	**Article 33**
Information obligation on notified bodies	
/	**Article 35**

4.2. Recreational crafts

National transposition:

[Loi du 23 décembre 2016 relative aux bateaux de plaisance et aux véhicules nautiques]
[Règlement grand-ducal du 23 décembre 2016 portant abrogation du règlement grand-ducal modifié du 8 septembre 1997 portant application de la directive 94/25/CE du Parlement européen et du Conseil du 16 juin 1994 concernant le rapprochement des dispositions législatives, réglementaires et administratives des Etats membres relatives aux bateaux de plaisance.]

Luxembourg notified body:

SNCH (Recreational craft/ Personal watercraft: A1, B, D, E, F, G, H; Components: B, D, F, G, H; Exhaust emissions: B, D, E, F, G, H; Noise emissions: A1, G, H)

Recreational craft/ Personal watercraft

Module A1. Internal production control	**Module B.** Type examination				**Module G.** Unit verification	**Module H.** Full quality assurance
	Module C. Conformity to type	**Module D.** Production quality assurance	**Module E.** AQ du produit	**Module F.** Product verification		

Components

Module A1. Internal production control	**Module B.** Type examination				**Module G.** Unit verification	**Module H.** Full quality assurance
	Module C. Conformity to type	**Module D.** Production quality assurance	**Module E.** AQ du produit	**Module F.** Product verification		

Exhaust emissions

Module A1. Internal production control	**Module B.** Type examination				**Module G.** Unit verification	**Module H.** Full quality assurance
	Module C. Conformity to type	**Module D.** Production quality assurance	**Module E.** AQ du produit	**Module F.** Product verification		

Noise emissions

Module A1. Internal production control	**Module B.** Type examination				**Module G.** Unit verification	**Module H.** Full quality assurance
	Module C. Conformity to type	**Module D.** Production quality assurance	**Module E.** AQ du produit	**Module F.** Product verification		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 94/25/EC	**Directive 2013/53/UE** *Applicable from 18th January 2016*
Conformity assessment procedures	
Annex V Internal production control (A)	**Article 20** Design and construction **Article 22** Noise emissions **- module A** Internal production control.
Annex VI Internal production control plus tests (A*bis*)	**Article 20** Design and construction **Article 22** Noise emissions **- module A1** Internal production control plus supervised product testing. The possibility of using accredited in-house bodies referred to in Modules A1 and C1 of Annex II to Decision No 768/2008/EC shall not be applicable. **Annexe VI** Additional requirements In the cases referred to in Article 24(2).
Annex VII EC type-examination (B)	**Article 20** Design and construction **Article 21** Exhaust emissions **- module B** EU type-examination. The EU type examination shall be carried out in the manner specified in the second indent of point 2 of that module.
Annex VIII Conformity to type (C)	**Article 20** Design and construction **Article 21** Exhaust emissions **- module C** Conformity to type based on internal production control. The possibility of using accredited in-house bodies referred to in Module C1 of Annex II to Decision No 768/2008/EC shall not be applicable. **Annexe VIII** Additional requirements in the cases referred to in Article 24(5).

Annex IX Production quality assurance (D)	**Article 20** Design and construction **Article 21** Exhaust emissions **- module D** Conformity to type based on quality assurance of the production process.
Annex X Product verification (F)	**Article 20** Design and construction **Article 21** Émissions gazeuses **- module F** Conformity to type based on product verification. **Annexe VII** Conformity of production assessment for exhaust and noise emission in the cases referred to in Article 24(4).
Annex XI Unti verification (G)	**Article 20** Design and construction **Article 21** Exhaust emissions **Article 22** Noise emissions **- module G** Conformity based on unit verification.
Annex XII Full quality assurance (H)	**Article 20** Design and construction **Article 21** Exhaust emissions **Article 22** Noise emissions **- module H** Conformity based on full quality assurance.
Annex XVI Product quality assurance (E)	**Article 20** Design and construction **Article 21** Exhaust emissions **- module E** Conformity to type based on product quality assurance.
Requirements relating to notified bodies	
Annex XIV	**Article 30**
>>> see analysis in the annex of the present document <<<	
Operational obligations of notified bodies	
/	**Article 38**
Information obligation on notified bodies	
/	**Article 40**

4.3. Simple pressure vessels

National transposition: Loi du 27 juin 2016 concernant la mise à disposition sur le marché des récipients à pression simples
Règlement grand-ducal du 27 juin 2016 portant abrogation du règlement grand-ducal modifié du 2 juillet 1992 relatif aux récipients à pression simples

Luxembourg notified body: Luxcontrol (B, C, C1, C2)

Module A. Internal production control	Module B. Type examination				Module G. Unit verification	Module H. Full quality assurance
	Module C. Conformity to type	Module D. Production quality assurance	Module E. Product quality assurance	Module F. Product verification		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 2009/105/EC (ex-87/404/EEC)	Directive 2014/29/UE *Applicable from 20th April 2016.*
Conformity assessment procedures	
Article 10 Examen «CE» de type (B)	**Annex II Module B** Examen UE de type
Article 11 Vérification «CE» (F)	
Articles 12-14 Déclaration de conformité «CE» (C)	**Annex II Module C** Conformité au type sur la base du contrôle interne de la fabrication
	Annex II Module C1 Conformité au type sur la base du contrôle interne de la fabrication et de l'essai supervisé du récipient
	Annex II Module C2 Conformité au type sur la base du contrôle interne de la production et de contrôles supervisés du produit à des intervalles aléatoires
Requirements relating to notified bodies	
Annex III	**Article 21**
>>> see analysis in the annex of the present document <<<	
Operational obligations of notified bodies	
/	**Article 29**
Information obligation on notified bodies	
/	**Article 31**

4.4. Non-automatic weighing instruments

National transposition: Règlement grand-ducal du 26 janvier 2016 concernant les instruments de pesage à fonctionnement non automatique

Luxembourg notified body: Service de métrologie (module F)

Module A. Internal production control	**Module B.** Type examination				Module G. Unit verification	Module H. Full quality assurance
	Module C. Conformity to type	**Module D.** Production quality assurance	Module E. Product quality assurance	**Module F.** Product verification		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 2009/23/EC (ex-90/384/EEC)	Directive 2014/31/UE *Applicable from 20th April 2016.*
Conformity assessment procedures	
Annex II.1. EC type-examination (B)	**Annex II Module B** EU-type examination
Annex II.2. Guarantee of production quality (D)	**Annex II Module D** Conformity to type based on quality assurance of the production process
	Annex II Module D1 Quality assurance of the production process
Annex II.3. EC Verification (F)	**Annex II Module F** Conformity to type based on product verification
	Annex II Module F1 Conformity based on product verification
Annex II.4. EC unit verification (G)	**Annex II Module G** Conformity based on unit verification
Annex II.5. Common provisions	
Requirements relating to notified bodies	
Annex V	**Article 23**
	A conformity assessment body shall be established under the national law of a Member State and have legal personality.
The bodies shall have at their disposal the necessary personnel, means and equipment.	A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annex II and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and each kind or category of instruments in relation to which it has been notified, a conformity

	assessment body shall have at its disposal the necessary: a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks; b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities; c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the instrument technology in question and the mass or serial nature of the production process. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
The personnel of the bodies shall have technical competence and professional integrity.	Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities. 7. The personnel responsible for carrying out conformity assessment tasks shall have the following: a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified; b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments; c) appropriate knowledge and understanding of the essential requirements set out in Annex I, of the applicable harmonised standards and of the relevant provisions of Union harmonisation legislation and of national legislation; d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
The bodies shall work independently of all circles, groups or persons having a direct or indirect interest in nonautomatic weighing instruments as regards the carrying-out of the tests, the preparation of the reports,	A conformity assessment body shall be a third-party body independent of the organisation or the instrument it assesses. A body belonging to a business association or professional federation representing undertakings

the issuing of the certificates and the surveillance required by this Directive.	involved in the design, manufacturing, provision, assembly, use or maintenance of instruments which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the instruments which they assess, nor the representative of any of those parties. This shall not preclude the use of assessed instruments that are necessary for the operations of the conformity assessment body or the use of such instruments for personal purposes. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those instruments, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed. The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
The personnel of the bodies shall respect professional confidentiality.	The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annex II or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
The bodies shall take out a civil liability insurance if their	Idem.

civil liability is not covered by the State under national law.	
	Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Union harmonisation legislation and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
Operational obligations of notified bodies	
/	**Article 31**
Information obligation on notified bodies	
/	**Article 33**

4.5. Lifts

National transposition: [Loi du 27 mai 2016 concernant les ascenseurs et les composants de sécurité pour ascenseurs et modifiant la loi modifiée du 15 décembre 2010 relative à la sécurité des jouets]

Luxembourg notified body: AIB-Vinçotte (annex V)

Module A. Internal production control	**IV Module B.** Type examination					**VIII Module G.** Unit verification	**VII/ XI Module H/ H1.** Full quality assurance
	IX Module C2. Conformity to type	**XII Module D.** Production quality assurance	**VI Module E.** Product quality assurance	Module F. Product verification	V Final inspection		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Luxcontrol (annexes V et VIII)

Module A. Internal production control	**IV Module B.** Type examination					VIII **Module G.** Unit verification	**VII/ XI Module H/ H1.** Full quality assurance
	IX Module C2. Conformity to type	**XII Module D.** Production quality assurance	**VI Module E.** Product quality assurance	Module F. Product verification	V Final inspection		

Directive 95/16/EC	Directive 2014/33/UE *Applicable from 20th April 2016*
Conformity assessment procedures	
Annex V EC type-examination (B)	**Annex IV** EU type-examination for lifts and safety components for lifts (B)
Annex VI Final inspection	**Annex V** Final inspection for lifts
Annex VIII Product quality assurance (E)	**Annex VI** Conformity to type based on product quality assurance for safety components for lifts (E)
Annex IX Full quality assurance (H)	**Annex VII** Conformity based on full quality assurance for safety components for lifts (H)
Annex X Unit verification (G)	**Annex VIII** Conformity based on unit verification for lifts (G)
Annex XI Conformity to type with random checking (C)	**Annex IX** Conformity to type with random checking for safety components for lifts (C2)
Annex XII Product quality assurance for lifts (E)	**Annex X** Conformity to type based on product quality assurance for lifts (E)

Annex XIII Full quality assurance for lifts (H)	**Annex XI** Conformity based on full quality assurance plus design examination for lifts (H1)
Annex XIV Production quality assurance (D)	**Annex XII** Conformity to type based on production quality assurance for lifts (D)
Requirements relating to notified bodies	
Annex VII	**Article 24**
>>> see analysis in the annex of the present document <<<	
Operational obligations of notified bodies	
/	**Article 32**
Information obligation on notified bodies	
/	**Article 34**

4.6. Pressure equipment

National transposition: [Loi du 27 juin 2016 concernant la mise à disposition sur le marché des équipements sous pression] [Règlement grand-ducal du 27 juin 2016 abrogeant le règlement grand-ducal du 21 janvier 2000 concernant les équipements sous pression]

Luxembourg notified body: Luxcontrol (modules A2, B, C2, D, D1, E, E1, F, G, H, H1)

Module A2. Internal production control	**Module B.** Type examination				**Module G.** Unit verification (includes permanent joining)	**Module H, H1.** Full quality assurance
	Module C2. Conformity to type	**Module D, D1.** Production quality assurance	**Module E, E1.** Product quality assurance	**Module F.** Product verification		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 97/23/EC	**Directive 2014/68/UE** *Applicable from 19th July 2016.* *Article 13 is applicable from 1st June 2015.*
Conformity assessment procedures	
Module A internal production control	**Annex III Module A** internal production control
Module A1 internal manufacturing checks with monitoring of the final assessment	**Annex III Module A2** Contrôle interne de la fabrication et contrôles supervisés de l'équipement sous pression à des intervalles aléatoires
Module B EC type-examination	**Annex III Module B** EU type-examination
Module B1 EC design-examination	
Module C1 conformity to type	**Annex III Module C2** Conformity to type based on internal production plus supervised pressure equipment checks at random intervals
Module D production quality assurance	**Annex III Module D** Conformity to type based on quality assurance of the production process
Module D1 production quality assurance	**Annex III Module D1** Quality assurance of the production process
Module E product quality assurance	**Annex III Module E** Conformity to type based on pressure equipment quality assurance

Module E1 product quality assurance	**Annex III Module E1** Quality assurance of final pressure equipment inspection and testing
Module F product verification	**Annex III Module F** Conformity to type based on pressure equipment verification
Module G EC unit verification	**Annex III Module G** Conformity based on unit verification
Module H full quality assurance	**Annex III Module H** Conformity based on full quality assurance
Module H1 full quality assurance with design examination and special surveillance of the final assessment	**Annex III Module H1** Conformity based on full quality assurance plus design examination
Article 11 European approval for materials	**Article 15** European approval for materials
Annex I, 3.1.2 Permanent joining	**Annex I, 3.1.2** Permanent joining
Requirements relating to notified bodies	
Annex IV	**Article 24**
>>> see analysis in the annex of the present document <<<	
Operational obligations of notified bodies	
/	**Article 34**
Information obligation on notified bodies	
/	**Article 36**

4.7. Noise emission in the environment by equipment for use outdoors

National transposition: Règlement grand-ducal du 21 décembre 2001 relatif aux émissions sonores, tel que modifié

Luxembourg notified body: SNCH (annexes VI-IX)

V/VI **Module A.** Internal production control	**Module B.** Type examination				VII **Module G.** Unit verification	VIII **Module H.** Full quality assurance
	Module C. Conformity to type	**Module D.** Production quality assurance	**Module E.** Product quality assurance	**Module F.** Product verification		

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 2000/14/EC
Conformity assessment procedures
Annex V Internal control of production (A)
Annex VI Internal control of production with assessment of technical documentation and periodical checking (A*bis*)
Annex VII Unit verification (G)
Annex VIII Full quality assurance (H)
Requirements relating to notified bodies
Annex IX
1) The body, its director and its staff responsible for carrying out verification operations may be neither the designer, builder, supplier or installer of the equipment nor the authorised representative of any of those parties. They may become involved neither directly nor as authorised representatives in the design, construction, marketing or maintenance of such equipment nor represent the parties engaged in these activities. This does not preclude the possibility of exchange of technical information between the manufacturer and the body.
2) The body and its staff must carry out the assessments and verifications with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their work, especially from persons or groups of persons with an interest in the results of verification.
3) The body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the technical and administrative tasks connected with inspection and surveillance operations; it must also have access to the equipment required for any special verification.
4) The staff responsible for inspection must have: - sound technical and professional training, - satisfactory knowledge of the requirements for the assessment of technical documentation, - satisfactory knowledge of the requirements for the tests they carry out and adequate practical experience of such tests, - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

5) The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or the results of such tests.
6) The body must take out liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.
7) The staff of the body must observe professional secrecy with regard to all information gained in carrying out its tests (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provisions of national law giving effect to it.

4.8. Construction products

Luxembourg notified body: LQMS (system 2+)

Systems of assessment and verification of constancy of performance		Certificate of constancy of performance of the product		Certificate of conformity of the factory production control	No certification	
		1+	**1**	**2+**	**3**	**4**
Manufacturer's tasks						
1	Sampling for determination of the product-type				M	
	Determination of the product-type on the basis of type-testing, type calculation, tabulated values or escriptive documentation of the product			M		M
2	Factory production control	M	M	M	M	M
3	Further testing of samples taken at the factory according to the prescribed test plan	M	M	M		
CAB's tasks						
4	Sampling for determination of the product-type	PCB	PCB			
	Determination of the product-type on the basis of type-testing, type calculation, tabulated values or escriptive documentation of the product	TCB	TCB		L	
5	Initial inspection of factory and of factory production control	IB	IB	IB		
6	Continuous surveillance, assessment and evaluation of factory production control	IB	IB	IB		
7	Audit-testing of samples taken before placing the product on the market	OI / TCB				

M	Manufacturer
PCB	Product certification body
IB	Inspection body under the responsibility of the product certification body
TCB	Testing laboratory under the responsibility of the certification body
L	Testing laboratory

Adapted from www.cstc.be (Centre Scientifique et Technique de la Construction).

Regulation (EU) N° 305/2011
Conformity assessment procedures
Annex I System 1+
Annex I System 1
Annex I System 2+
Annex I System 3
Annex I System 4
Requirements relating to notified bodies
Article 43
1) For the purposes of notification, a notified body shall meet the requirements set out in paragraphs 2 to 11.
2) A notified body shall be established under national law and have legal personality.
3) A notified body shall be a third-party body independent from the organisation or the construction product it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of construction products which it assesses, can on condition that its independence and the absence of any conflict of interest are demonstrated, be considered to be such a body..
4) A notified body, its top-level management and the personnel responsible for carrying out the third party tasks in the process of assessment and verification of constancy of performance shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the construction products which it assesses, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the notified body or the use of products for personal purposes. A notified body, its top-level management and the personnel responsible for carrying out the third party tasks in the process of assessment and verification of constancy of performance shall not become directly involved in the design, manufacture or construction, marketing, installation, use or maintenance of those construction products, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement and integrity related to the activities for which they have been notified. This shall, in particular, apply to consultancy services. A notified body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its assessment and/or verification activities.
5) A notified body and its personnel shall carry out the third party tasks in the process of assessment and verification of constancy of performance with the highest degree of professional integrity and requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their assessment and/or verification activities, especially from persons or groups of persons with an interest in the results of those activities.
6) A notified body shall be capable of carrying out all the third party tasks in the process of assessment and verification of constancy of performance assigned to it in accordance with Annex V in relation to which it has been notified, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility. At all times and for each system of assessment and verification of constancy of performance and for each kind or category of construction products, essential characteristics and tasks in relation to which it has been notified, the notified body shall have the following at its disposal: a) the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the third party tasks in the process of assessment and verification of constancy of performance; b) the necessary description of procedures according to which the assessment of performance is carried out, ensuring the transparency and the ability of reproduction of these procedures; it shall have appropriate policies

and procedures in place that distinguish between the tasks it carries out as a notified body and other activities; c) the necessary procedures to perform its activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process. A notified body shall have the means necessary to perform the technical and administrative tasks connected with the activities for which it is notified in an appropriate manner and shall have access to all necessary equipment or facilities.
7) The personnel responsible for carrying out the activities in relation to which the body has been notified, shall have the following: a) sound technical and vocational training covering all the third party tasks in the process of assessment and verification of constancy of performance within the relevant scope for which the body has been notified; b) satisfactory knowledge of the requirements of the assessments and verifications they carry out and adequate authority to carry out such operations; c) appropriate knowledge and understanding of the applicable harmonised standards and of the relevant provisions of the Regulation; d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments and the verifications have been carried out.
8) The impartiality of the notified body, its top-level management and assessment personnel shall be guaranteed. The remuneration of the notified body's top-level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.
9) A notified body shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the assessment and/or the verification performed.
10) The personnel of the notified body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under Annex V, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
11) A notified body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body coordination group established under this Regulation and shall apply as general guidance the administrative decisions and documents produced as a work result of that group.
Operational obligations of notified bodies
Article 52
Information obligation on notified bodies
Article 53

4.9. Personal protective equipment

National transposition: [Règlement grand-ducal du 10 août 1992 relatif aux équipements de protection individuelle, tel que modifié]

Luxembourg notified body: SNCH (Art. 10, 11A and 11B)

IV Module A. Internal production control	**V Module B.** Type examination			**Module G.** Unit verification	**Module H.** Full quality assurance
	VI, VII Module C, C2. Conformity to type	**IV Module D.** Production quality assurance	**Module E.** Product quality assurance	**Module F.** Product verification	

Green background: module for which the CAB is notified; white background: module for which the CAB is not notified; grey shaded background: module not present in the directive.

Directive 89/686/EEC	**Regulation (EU) N° 2016/425** *Applicable from 21st April 2018.* *Articles 20 to 36 and 44 are applicables from 21st October 2016.* *Article 45, paragraph 1, is applicable from 21st March 2018.*
Conformity assessment procedures	
/	**Annexe IV Module A** Internal production control
Art 10) « EC » quality control system for the final product.	**Annexe V Module B** EU type-examination
I	**Annexe VI Module C** Conformity to type based on internal production control
Art 11 A) Checking of PPE manufactured: 'EC' quality control system for the final product.	**Annexe VII Module C2** Conformity to type based on internal production control plus supervised product checks at random intervals
Art 11 B) Checking of PPE manufactured: System for ensuring EC quality of production by means of monitoring.	**Annexe VIII Module D** Conformity to type based on quality assurance of the production process
Art 12 EC declaration of product conformity.	Article 15
Requirements relating to notified bodies	
Annex V	**Article 24**
	2. A conformity assessment body shall be established under the national law of a Member State and have legal personality.
3) indépendance (quant à l'exécution des essais, à l'élaboration des rapports, à la délivrance des	3. A conformity assessment body shall be a third-party body independent of the organisation or the PPE it

attestations et à la réalisation de la surveillance, prévues par la directive) des cadres et du personnel technique par rapport à tous les milieux, groupements ou personnes, directement ou indirectement intéressés au domaine des EPI;	assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of PPE which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body. 4. A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities. 8. The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed. The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.
2) compétence technique et intégrité professionnelle du personnel;	5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities. 7. The personnel responsible for carrying out conformity assessment tasks shall have the following: a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

	b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments; c) appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, and of the relevant provisions of Union harmonisation legislation and of national legislation; d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.
1) disponibilité en personnel ainsi qu'en moyens et équipements nécessaires;	6. A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes V, VII and VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and each kind of PPE for which it has been notified, a conformity assessment body shall have at its disposal the necessary: a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks; b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities; c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process. A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
5) souscription d'une assurance de responsabilité civile, à moins que cette responsabilité ne soit couverte par l'État sur la base du droit national.	Idem (9.).
4) respect du secret professionnel par le personnel;	10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes V, VII and VIII or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected
	11. Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities

	of the notified body coordination group established under Article 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.
Operational obligations of notified bodies	
/	**Article 32**
Information obligation on notified bodies	
/	**Article 34**

Annex: Comparison of requirements relating to notified bodies

The Table below highlights the modification concerning requirements relating to notified bodies following alignment of directives concerning recreational crafts, pressure equipment, pyrotechnic articles and simple pressure vessels with the decision n° 768/2008/EC.

Former directives	Novelties of the decision n° 768/2008/EC
	For the purposes of notification, a conformity assessment body shall meet the following requirements.
	A conformity assessment body shall be established under national law and have legal personality.
The body, its director and the staff responsible for carrying out the verification tests must not be the designer, manufacturer, supplier, installer or importer (pyrotechnic articles) or user (pressure equipment) of pyrotechnic articles which they inspect, nor the authorised representative of any of these parties. They must not become involved either directly or as authorised representative in the design, construction, marketing, maintenance or importation of such articles, nor represent the parties engaged in these activities (pressure equipment). This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.	The term *director* is replaced by *top level management*. It is added that a A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services. Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered as fulfilling the requirement that a conformity assessment body shall be a third-party body independent of the organisation or the product it assesses (recreational crafts, pressure equipment).
The body and its staff must carry out the verification tests with the highest degree of professional integrity and technical competence and must be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.	Idem.

The body must have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it must also have access to the equipment required for special verification.	The expression *access to the equipment required for special verification* is replaced by *access to all necessary equipment or facilities*. It is added that a conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by … [reference to relevant part of the legislation] and in relation to which it has been notified whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary: a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks; b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities; c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process. It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.
The staff responsible for inspection must have: - sound technical and professional training, - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests, - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.	It is specified that training must cover all the conformity assessment activities in relation to which the conformity assessment body has been notified. The expression *required to authenticate the performance of the tests* is replaced by *demonstrating that assessments have been carried out*.
The impartiality of inspection staff must be guaranteed. Their remuneration must not depend on the number of tests carried out or on the results of such tests.	The words *inspection staff* are replaced by *conformity assessment bodies, their top level management and the assessment personnel*.
The body must take out civil liability insurance unless its liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the tests.	Idem.

The staff of the body must observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under this Directive or any provision of national law giving effect to it.	Addition of the information that proprietary rights shall be protected.
	Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.