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**Regulatory policy**
**Regulatory Approach for the free circulation of goods**

**NOTE TO THE SENIOR OFFICIALS GROUP ON STANDARDISATION AND CONFORMITY ASSESSMENT POLICY**

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| **Title:** | **CERTIF 2009–04**<br>INTRODUCTION TO CONFORMITY ASESSMENT AND CONFORMITY ASSESSMENT PROCEDURES OF THE NEW LEGAL FRAMEWORK (AS LAID DOWN IN DECISION 768/2008 OF THE NEW LEGAL FRAMEWORK) | | |
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**Abstract:**

**This document is addressed to newcomers into conformity assessment and:**

- **explains what is conformity assessment,**
- **describes its mechanisms and its role in the supply chain of a product**
- **explains the role of the stakeholders and**
- **provides a detailed analysis of the conformity assessment procedures as defined in the Decision No 768/2008/EC (OJ L218, page 82 of 13 August 2008)**

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| **Keywords:** | **Conformity assessment modules/procedures, accreditation, manufacturers, conformity assessment bodies, Notified Bodies, Notifying authorities,** |
| **References:** | **Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (OJ L218, page 30 of 13 August 2008)**<br>**Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products (OJ L218, page 82 of 13 August 2008)** |

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Brussels, 19th Januray2009

# SUBJECT: INTRODUCTION TO CONFORMITY ASESSMENT AND CONFORMITY ASSESSMENT PROCEDURES OF THE NEW LEGAL FRAMEWORK (AS LAID DOWN IN DECISION 768/2008 OF THE NEW LEGAL FRAMEWORK)

## 0. Contents

## 1. Introduction to the context - What is conformity assessment?

Two most important elements of the New Legal Framework (NLF) directives are

- the essential requirements governing the characteristics of the products covered
- and the conformity assessment procedures required to demonstrate that a product, before it is placed into the market, conforms to these essential requirements of the directive that apply to it.

Conformity assessment must not be confused with market surveillance, which consists of controls after the product has been placed into the market. However both techniques are complementary and equally necessary to ensure the smooth functioning of the internal market.

In the context of the New Approach and the New Legal Framework the idea behind conformity assessment is that the legislator requires an "assurance/proof" from the manufacturer that his products fulfil the requirements of the legislative instruments that apply to them, prior to their placing on the market.

## 2. Stakeholders and components in conformity assessment – Who is doing what? What is the position of conformity assessment in the supply chain?

In the context of NLF, the assessment of the conformity of a product is carried out before this product is placed on the market and consists in demonstrating that it fulfils all the legislative requirements that apply to it. The essential objective of a conformity assessment procedure is to demonstrate to public authorities that products placed on the market conforms to the requirements as expressed in the provisions of the relevant legislation, in particular with regard to the health and safety of users and consumers.

Conformity assessment is performed following technical procedures which are specified in the sectoral legislation. Conformity assessment procedures are composed of one or two conformity assessment modules. A conformity assessment procedure covers both design and production phases; while a module may cover either one of these two phases (in this case a conformity assessment procedure is composed of two modules) or both (in this case a conformity assessment procedure is composed of one module).

All procedures/modules are set out in the New Legal Framework and serve for the sectoral legislator as a simple, coherent and complete menu to select the most appropriate module(s)/procedure(s) for the specific area of activity.

All procedures for demonstrating compliance with regulatory requirements are considered as leading to the same level of conformity.

The assessment of the conformity of the product in question may be carried out either by the manufacturer himself or by (manufacturer's in-house or external) conformity assessment body, depending on the provisions of the modules selected by the relevant sectoral legislative instrument. In this respect there are three possibilities (under some modules the sectoral legislator may allow the manufacturer to choose or he may impose the intervention of an external conformity assessment body):

- Conformity assessment is performed by the manufacturer himself. This may concern the case where, according to the legislator, a statement (accompanied by the relevant technical examinations and documentation) of the manufacturer is enough to ensure the conformity of the product(s) in question against the relevant legislative requirements. This may be the case for products of low risk and complexity. In this case the manufacturer himself carries out all controls and checks a conformity assessment body would do.

- Conformity assessment is performed by an accredited in-house conformity assessment body that forms a part of the manufacturer's organisation. However this in-house body must not have any activities other than conformity assessment and must be independent from any commercial, design and production entities (see also Art R21 of Decision 768/2008/EC[1]).

  Quite often, the legislator acknowledges the fact that manufacturers manage very well equipped testing laboratories or premises and their competence is sometimes higher than the abilities of certain external bodies. This may be the case for new innovative complex products for which the testing know-how remains inside the manufacturers.

  A typical example is innovative SMEs active in the area of new materials. SMEs benefit particularly from the use of an accredited in-house body, because due to their size, they monitor more closely their testing mechanisms and facilities than bigger companies do.

- However in many other cases the legislator may consider the intervention of an external conformity assessment body necessary. Such a body must be impartial and independent from the organisation or the product it assesses (see also Art R17.3 of Decision 768/2008/EC), it cannot engage in any activity that may conflict with its independence of judgment (see also Art R21.2.c of Decision 768/2008/EC) and thus it cannot have user or other interests in the product to be assessed

In the Council Decision 768/2008/EC, it is the responsibility of the Member States to notify those external conformity assessment bodies within their jurisdiction that are technically competent to assess the compliance of products with the requirements of the directives(s) that apply to them. In-house bodies do not need to be notified but they have still to demonstrate the same technical competence as external bodies. Member States must also ensure that the (in-house or external) bodies permanently maintain their technical competence.

Taking the above into account, the stakeholders in a conformity assessment procedure are the following

2.1) The sectoral legislator who:

- sets out the legal requirements that products have to fulfil
- selects conformity assessment modules/procedures from the menu set out under NLF

[1] Decision of the European Parliament and the Council on a common framework for the marketing of products

2.2) The manufacturer who:

- designs, manufactures and tests the product
- drafts the technical documentation of the product. The format of the technical documentation is based on EN ISO standards
- takes all measures necessary so that the manufacturing process ensures compliance of the products
- if the relevant legislation provides for, it may perform the assessment of the conformity of his products
- upon positive assessment of the products, draws up the declaration of conformity and affixes the required conformity marking on the products. By doing these, the manufacturer ensures and declares under his sole responsibility (and independent of the fact of whether the conformity assessment has been performed by him or a conformity assessment body) that the products concerned satisfy the requirements of the legislative instrument(s) that apply to them (this may be done also by the authorised representative).
- upon intervention of a notified body, affixes the notified body's identification number to the product

It must be clear that it is always the manufacturer who guarantees to the market and to the public authorities the conformity of his products to the relevant legislative requirements.

The format of the EC declaration of conformity is laid down in Annex III of the Decision and is based on EN ISO standards. The declaration of conformity must be at the disposal of public authorities immediately upon request.

2.3) The (in-house or external) conformity assessment body that:

- performs the conformity assessment, if the legislation provides so
- upon positive assessment issues an approval

A conformity assessment body wishing to offer services for one or several module(s) under a directive in the sense of “one stop testing and certification” needs to be assessed according to the requirements for the different modules it wishes to offer services for. A body wishing to offer conformity assessment services under a directive will need to offer services for at least one module from those indicated in the directive. It should be noted that there is no obligation for a body to offer services for more than one module, but it must take on the responsibility for a whole module if it wishes to offer services.

The criteria conformity assessment bodies must fulfil in order to be positively assessed are the same for in-house or external ones and are set out in EN ISO and EN standards.

It is the assessment of the conformity assessment body that will determine if it is technically competent and capable of carrying out the conformity assessment procedures it wishes to offer services for. Equally important is the continuous surveillance of the competence of the body. Both evaluation and continuous surveillance should follow the practices established by the national accreditation

organisations and harmonised at European level through European co-operation for Accreditation (EA)

In this respect, the national notifying authorities may demonstrate the technical competence of conformity assessment body either by the accreditation certificate or by an evaluation and surveillance by the national notifying authorities themselves that follow the methods and criteria established by the national accreditation organisations. In practice the latter way is almost never used.

Art 4.7 of the Decision stipulates that an appeal procedure against decisions of the notified body must exist.

2.4) The national accreditation organisations (one per Member State) that:

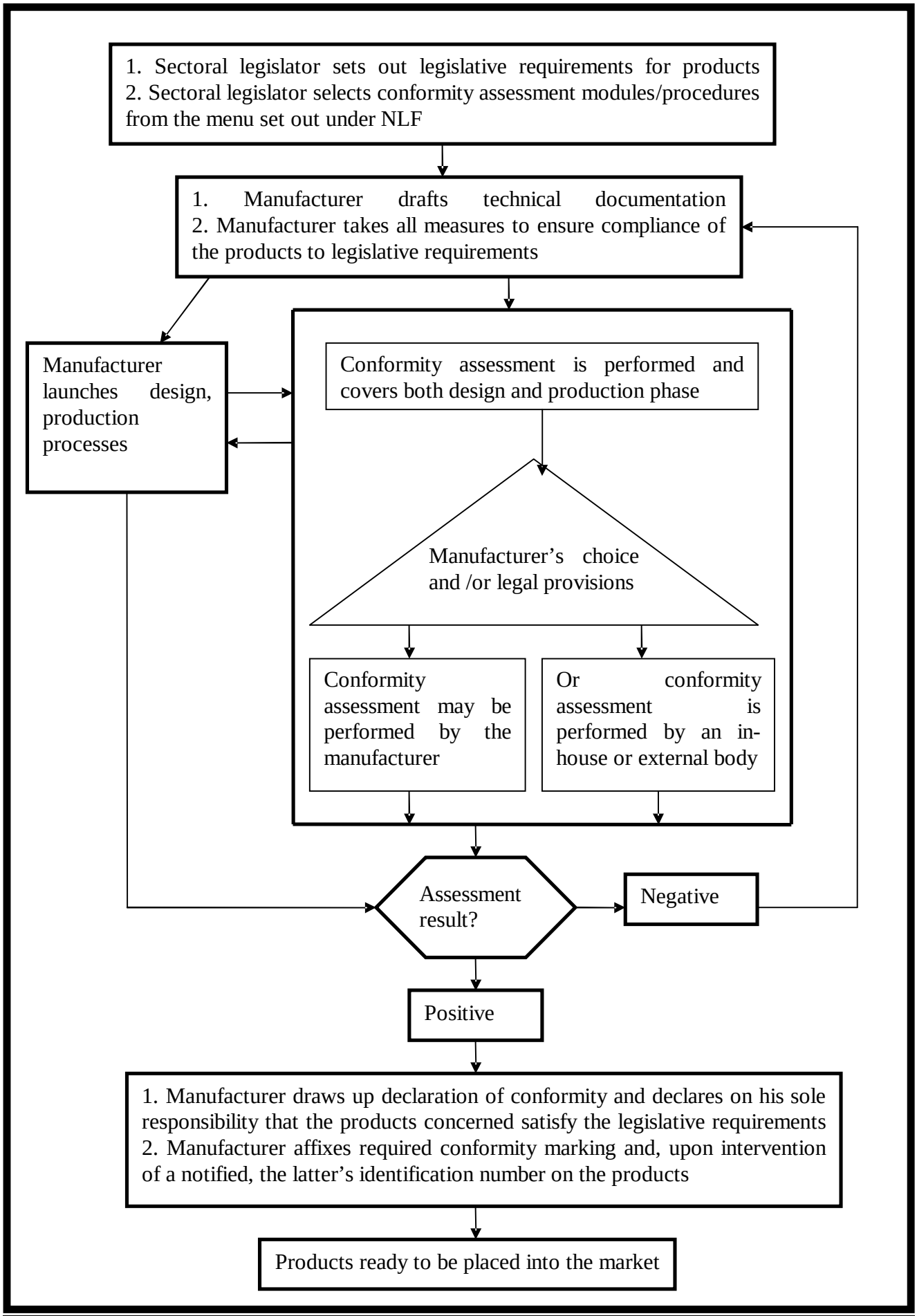
- evaluate and survey the competence of the conformity assessment bodies and
- upon positive evaluation issue an accreditation certificate for the body in question.

National accreditation organisations must be able to demonstrate that they have the capability, in terms of management, organisation, trained staff (e.g. assessors), procedures etc. of evaluating the conformity assessment body. In order to build and maintain confidence between the Member States it is essential the accreditation bodies performing the assessment demonstrate an equivalent competence and operate according to the same criteria as set out in the relevant EN ISO standards. This is done by their participation in the peer evaluation system managed by EA.

2.5) The Notifying authorities of the Member States that:

- notify those external conformity assessment bodies of their choice within their jurisdiction that can demonstrate technical competence to assess the compliance of products with the requirements of the directives(s) that apply to them.

The exact position of conformity assessment in the supply chain is depicted under Flowchart 1


1. Sectoral legislator sets out legislative requirements for products
2. Sectoral legislator selects conformity assessment modules/procedures from the menu set out under NLF
1. Manufacturer drafts technical documentation
2. Manufacturer takes all measures to ensure compliance of the products to legislative requirements
Manufacturer launches design, production processes
Conformity assessment is performed and covers both design and production phase
Manufacturer's choice and /or legal provisions
Conformity assessment may be performed by the manufacturer
Or conformity assessment is performed by an in-house or external body
Assessment result?
Negative
Positive
1. Manufacturer draws up declaration of conformity and declares on his sole responsibility that the products concerned satisfy the legislative requirements
2. Manufacturer affixes required conformity marking and, upon intervention of a notified, the latter's identification number on the products
Products ready to be placed into the market

## 3. Competitiveness and conformity assessment

As already mentioned, in the context of the New Legislative Framework the legislator requires an "assurance" from the manufacturer that his products fulfil the requirements of the legislative instruments that apply to them. The legislator should restrict himself only to legislative requirements and avoid dictating to manufacturers any policies on how to meet market needs or be competitive.

However fulfilling the legislative requirements is a pre-condition but not enough to succeed on world markets. If product conformity with essential requirements is necessary and obligatory for reasons of health, safety and environmental and consumer protection, it is not necessarily enough to meet the needs of the market and therefore to deal successfully with competition.

In this respect it must be clear that if conformity assessment, as developed in the New Legislative Framework, is essential for the implementation of the internal market, it is not necessarily sufficient to the development of the competitiveness of European companies. Placing emphasis on the legislative aspects must not lead manufacturers to forget that they have to concentrate also on the essential questions of their overall quality management, i.e. modern organisational structures, effective manufacturing technologies, prompt availability of products and high standards after-sales service.

## 4. Conformity assessment procedures

### 4.1 General

As already stated, conformity assessment procedures are equivalent from a legal point of view but not technically identical in terms of methods. However, their application in practice is such that the result should be a sufficient level of confidence on all sides as regards the conformity of products to the relevant essential requirements

A product should be covered by conformity assessment both during the design and production phase. The directives specify the combination of modules, i.e. conformity assessment procedures, that cover both design and production phase and are available to the manufacturer to demonstrate conformity.

The intention of the new modules as laid down in the New Legal Framework is to allow for as limited number of procedures as possible. Nevertheless, the choice offered needs to be sufficiently varied as to be applicable to the widest range of products concerned.

### 4.2 Modules and their variants

Several modules have variants. The reason for providing variants within modules (this applies for all variants of all modules of NLF) is to enable that for products presenting higher levels of risk, the necessary level of protection is ensured, whilst avoiding to impose a more complicated module. Should these variants not exist, the legislator would have to opt for a procedure that is more burdensome for the manufacturers, but not necessarily appropriate for the safeguard of the required level of protection.

### 4.3 Modules based on quality assurance

Some modules and their variants are based on quality assurance techniques and are derived from the EN ISO 9000[2], EN ISO 9001[3] standards. The modules based on quality assurance techniques (modules D, E, H and their variants) describe the elements a manufacturer must implement in his organisation in order to demonstrate that the product fulfils the essential requirements of the applicable directive.

This means that a manufacturer is given the possibility of using an approved quality system that ensures that he has the capability to design (if applicable), manufacture and supply products that fulfil the applicable essential requirements.

Furthermore and under certain conditions this allows manufacturers to benefit from their investment in quality systems as it contributes to the improvement of the competitiveness of companies.

The quality system is assessed by the notified body. If the manufacturers' quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module. However, the manufacturer is free to apply other quality system models than those based on EN ISO 9001 for the purpose of complying with this module. In the latter case he must demonstrate that the quality system he operates is equivalent to EN ISO 9001.

### 4.4 One- and two-module procedures - Procedures based on prototype (EC-type examination)

In some cases (e.g. mass production based on a prototype/specimen "representative of the production envisaged") and where the product in question is of complex design, the legislator may lay down the conformity assessment procedure in two steps: first the examination of conformity of the prototype/specimen against the relevant legal requirements (so called EC-type examination - module B) and then the determination of the conformity of the products against the approved EC-type. In these cases conformity assessment procedures are composed of two modules; the first module is always module B.

This method not only reduces burden and costs but is also more efficient compared to a traditional examination of the conformity products directly against the legal requirements. Once the specimen type is approved (and this is done only once for a specific specimen), it must be checked only whether the products to be placed on the market are in conformity with the specimen.
In cases where there is no EC-type examination, conformity assessment procedures are composed of one two-phase (design & production) module.

### 4.5 Set of conformity assessment modules and procedures in NLF

- 4.5.1) The following modules exist under NLF:

[2] "Quality management systems — Fundamentals and vocabulary"

[3] Quality management systems — Requirements

A - Internal production control
A1 (variant of module A) - Internal production control plus supervised product checks
A2 (variant of module A) - Internal production control plus supervised product checks at random intervals

B - EC-type examination. Under Module B a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it by issuing an EC-type examination certificate. Module B is always followed by other modules by which the conformity of the products to the approved EC-type is demonstrated.

C - Conformity to type based on internal production control
C1 (variant of module C) - Conformity to type based on internal production control plus supervised product testing
C2 (variant of module C) - Conformity to type based on internal production control plus supervised product checks at random intervals

D - Conformity to type based on quality assurance of the production process (manufacturing part and inspection of final product)
D1 (variant of module D) - Quality assurance of the production process (manufacturing part and inspection of final product).
Module D1 in comparison to module D provides for additional provisions containing the supplementary requirement that the manufacturer must draw up the technical documentation of the product design. The technical documentation is examined by the notified body.

E - Conformity to type based on product quality assurance (like D without the manufacturing part)
E1 (variant of module E) - Quality assurance of final product inspection and testing (like D1 without the manufacturing part)
Module E1 in comparison to module E provides for additional provisions containing the supplementary requirement that the manufacturer must draw up the technical documentation of the product design. The technical documentation is examined by the notified body. (similar to D/D1).

F - Conformity to type based on product verification
F1 (variant of module F) - Conformity based on product verification
Module F1 in comparison to module F provides for additional provisions containing the supplementary requirement that the manufacturer must draw up the technical documentation of the product design. The technical documentation is examined by the notified body. (similar to D/D1, E/E1).

G - Conformity based on unit verification

H - Conformity based on full quality assurance
H1 (variant of module H) - Conformity based on full quality assurance plus design examination

- 4.5.2) Out of the above modules, the following procedures are possible:

A - Internal production control

A1 - Internal production control plus supervised product checks

A2 - Internal production control plus supervised product checks at random intervals

B+C - EC-type examination (B) followed by Conformity to EC-type based on internal production control (C)

B+C1- EC-type examination (B) followed by Conformity to EC-type based on internal production control plus supervised product testing (C1)

B+C2 - EC-type examination (B) followed by Conformity to EC-type based on internal production control plus supervised product checks at random intervals (C2)

B+D - EC-type examination (B) followed by Conformity to EC-type based on quality assurance of the production process (D)

D1 - Quality assurance of the production process.
As D1 requires from the manufacturer to draw up the technical documentation of the product design, the examination of the product design is carried out in the framework of D1. Therefore D1 does not need to be preceded by B.

B+E - EC-type examination (B) followed by Conformity to EC-type based on product quality assurance (E)

E1 - Quality assurance of final product inspection and testing
As E1 requires from the manufacturer to draw up the technical documentation of the product design, the examination of the product design is carried out in the framework of E1. Therefore E1 does not need to be preceded by B (similar to D/D1).

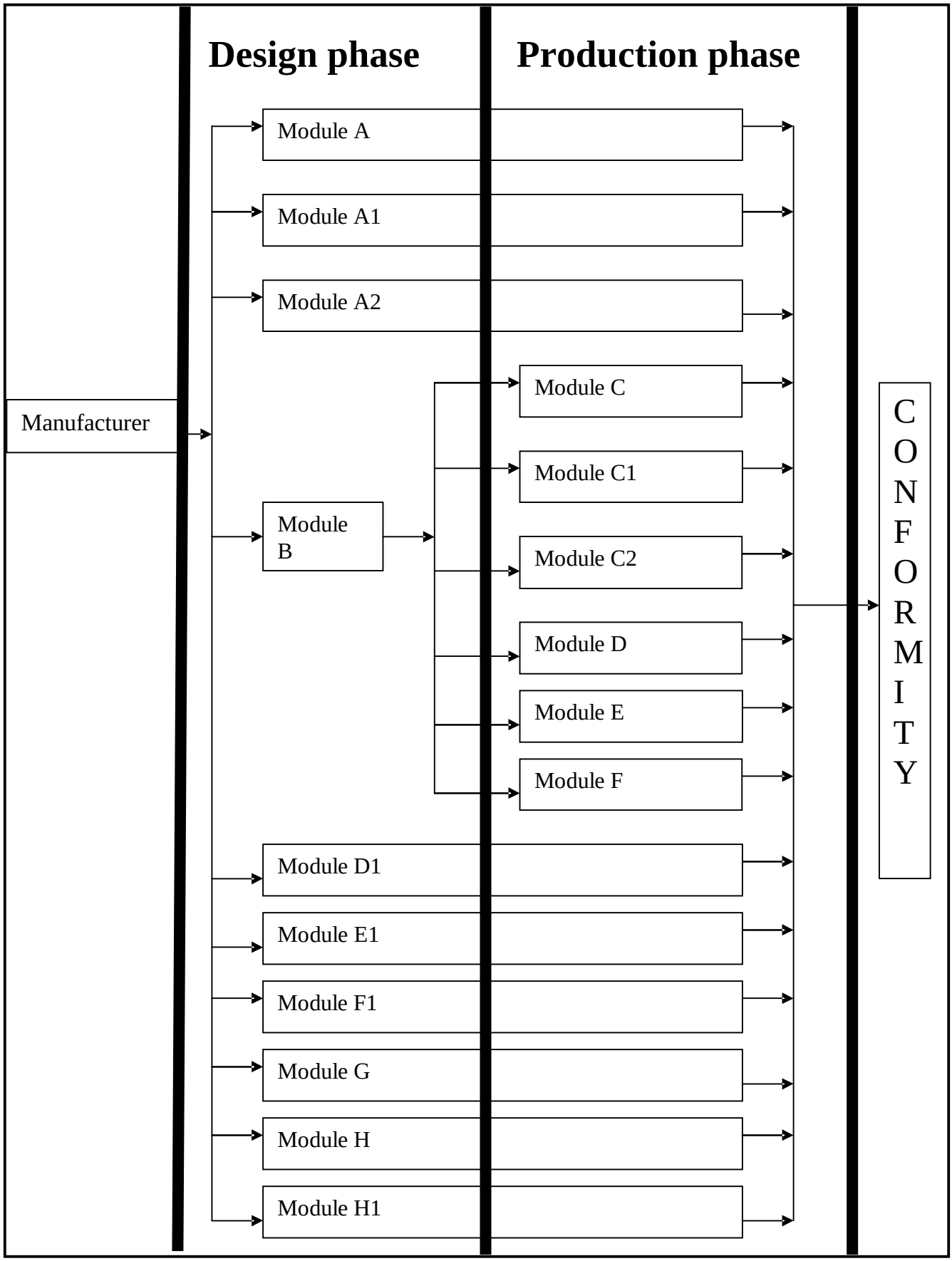
B+F - EC-type examination (B) followed by Conformity to EC-type based on product verification (F)

F1 - Conformity based on product verification
As F1 requires from the manufacturer to draw up the technical documentation of the product design, the examination of the product design is carried out in the framework of F1. Therefore F1 does not need to be preceded by B (similar to D/D1, E/E1).

G - Conformity based on unit verification

H - Conformity based on full quality assurance

H1 - Conformity based on full quality assurance plus design examination


Design phase
Production phase
Manufacturer
Module A
Module A1
Module A2
Module B
Module C
Module C1
Module C2
Module D
Module E
Module F
Module D1
Module E1
Module F1
Module G
Module H
Module H1
CONFORMITY

## 5. Detailed analysis of the conformity assessment modules

### 5.1 Module A (Internal production control)

Module A covers both design production phase.

The manufacturer ensures himself the conformity of the products to the legislative requirements.

In the design phase he:

- identifies the applicable requirements
- carries out an adequate analysis and assessment of the risk(s).

In the production phase he:

- takes all measures necessary so that the manufacturing process ensures compliance of the manufactured products with the legislative instruments that apply to them
- carries out detailed tests and controls
- monitors the compliance of the products

This module does not require a notified body to take action (first-party conformity assessment). However the manufacturer must carry out himself all checks a notified body would do.

## 5.2 Module A1 (Internal production control plus supervised product testing)

Module A1 is a variant of module A and covers both design production phase

Module A1 in comparison to module A provides for additional provisions containing the following supplementary requirements: for each individual product manufactured, one or more specific tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body (first-party conformity assessment) or under the responsibility of a notified body (third-party conformity assessment) chosen by the manufacturer. The products concerned and the applicable tests are specified in the directive (art 4.6.a of the Decision).

If the manufacturer decides for a notified body, the latter either carries out himself the tests, if the manufacturer so requests, or it supervises their execution. In either case the notified body must have the technical knowledge, experience and ability in carrying out the tests. Even if the test equipment is situated with the manufacturer, requirements on the equipment's suitability, functioning, maintenance (e.g. calibration programmes) and measurement traceability must be ensured and should be considered as the responsibility of the notified body. Furthermore, if the manufacturer has not applied the relevant harmonised standards, equivalent tests must be carried out, or failing this, appropriate methods must be developed. In either case, the notified body must validate the tests used.

Module A1 lays down an additional option for the legislator: the use of an accredited in-house body. Thus, the manufacturer could either carry out tests and product checks through and under the responsibility of a third-party (notified body chosen by the manufacturer), as is done currently, or to implement them by an accredited body that forms a part of manufacturer's organisation.

The reason is that quite often, manufacturers manage very well equipped testing laboratories or premises and their competence is sometimes higher than the abilities of certain notified bodies. Therefore the reliability of the tests and the level of safety could be even improved in this way. However, in this case the in-house body must be accredited. By allowing in-house assessment, the costs in administration and double testing would be reduced, which should result in reductions of the final price for users and consumers. It is necessary to stress that a specific sectoral legislative instrument remains free to require the use of an accredited third party where this is felt necessary (art 4.5.c of the Decision).

### 5.3 Module A2 (Internal production control plus supervised product checks at random intervals)

Module A2 is a variant of module A and covers both design production phase. The main idea behind module A2 is similar to the one of module A1

Module A2 in comparison to module A provides for additional provisions containing the following supplementary requirements: at the choice of the manufacturer, either an accredited in-house body (first-party conformity assessment) or a notified body (third-party conformity assessment), chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the product, taking into account inter alia the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product performs within acceptable limits, with a view to ensuring conformity of the product. According to art 4.6.a of the Decision, the legislative instrument must specify the appropriate tests, the adequate sampling schemes, the operational characteristics of the statistical method to be applied and the corresponding action to be taken by the notified body and/or the manufacturer

The term “acceptable” is used because a random sampling is a semi-statistical method and consists in picking up and testing samples and thus may perform only in acceptable limits.

Module A2 lays down an additional option for the legislator: the use of an accredited in-house body. Thus, the manufacturer could either carry out tests and product checks through and under the responsibility of a third-party (notified body chosen by the manufacturer), as is done currently, or to implement them by an accredited body that forms a part of manufacturer’s organisation.

The reason is that quite often, manufacturers manage very well equipped testing laboratories or premises and their competence is sometimes higher than the abilities of certain notified bodies. Therefore the reliability of the tests and the level of safety could be even improved in this way. However, in this case the in-house body must be accredited. By allowing in-house assessment, the costs in administration and double testing would be reduced, which should result in reductions of the final price for users and consumers. It is necessary to stress that a specific sectoral legislative instrument remains free to require the use of an accredited third party where this is felt necessary (art 4.5.c of the Decision).

## 5.4 Module B (EC-type examination)

Module B covers only the design phase.

EC-type examination is the part of a conformity assessment procedure in which a notified body (third-party conformity assessment) examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it by issuing an EC-type examination certificate. Module B is always followed by other modules by which the conformity of the products to the approved EC-type is demonstrated.

This examination may be carried out in either of the following manners (according to art 4.6.b of the Decision, the legislator determines the manner):

- examination of a specimen, representative of the production envisaged, of the complete product (production type - as existed under New Approach);

- assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type);

- assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence, without examination of a specimen (design type).

Module B, tackles the need for greater flexibility to be provided for, through the extension of the concept of type examination to include not only the production type examination (as already existed under New Approach) but also the options of examining only the technical documentation and/or critical parts of the specimen. This concept is based on the example of the Measuring Instruments Directive and is designed to provide sufficient flexibility to recognise relevant practice where the examination of a specimen "representative of the production envisaged" is either not economically viable or not necessary, such as for well-known products applying standard technology.

Remark: As module B covers only the design phase, the manufacturer does not draft any declaration of conformity at this stage of the process and may not affix the notified body's identification number to the product

## 5.5 Module C (Conformity to type based on internal production control)

Module C covers only the production phase and follows module B.

The manufacturer ensures himself the conformity of the products to the type described in the EC-type examination certificate and to the requirements of the legislative instrument that apply to them. Its common point with module A is that the manufacturer ensures himself the conformity of his products; however under module C this conformity is evaluated against an approved EC-type resulted under module B (this notion does not exist under module A and variants as they cover both design and production phase)

This module does not require a notified body to take action (first-party conformity assessment). However the manufacturer must carry out himself all checks a notified body would do.

## 5.6 Module C1 (Conformity to type based on internal production control plus supervised product testing)

Module C1 is a variant of module C and covers only the production phase, in a similar way module A1 is variant of module A. Under modules C/C1 the conformity is evaluated against an approved EC-type resulted under module B (this notion does not exist under modules A/A1 and variants as they cover both design and production phase)

Similar to modules A/A1, module C1 in comparison to module C provides for additional provisions containing the following supplementary requirements: for each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument.

The legislator allows manufacturer to make the choice s to whether the tests are carried out either by an accredited in-house body (first-party conformity assessment) or under the responsibility of a notified body (third-party conformity assessment) chosen by the manufacturer. The products concerned and the applicable tests are specified in the directive (art 4.6.a of the Decision).

If the manufacturer decides for a notified body, the latter either carries out the tests itself, if the manufacturer so requests, or it supervises their execution. In either case the notified body must have the technical knowledge, experience and ability in carrying out the tests.

Even if the test equipment is situated with the manufacturer, requirements on the equipment's suitability, functioning, maintenance (e.g. calibration programmes) and measurement traceability must be ensured and should be considered as the responsibility of the notified body. Furthermore, if the manufacturer has not applied the relevant harmonised standards, equivalent tests must be carried out, or failing this, appropriate methods must be developed. In either case, the notified body must validate the tests used.

Module C1 lays down an additional option for the legislator: the use of an accredited in-house body. Thus, the manufacturer could either carry out tests and product checks through and under the responsibility of a third-party (notified body chosen by the manufacturer), as is done currently, or to implement them by an accredited body that forms a part of manufacturer's organisation.

The reason is that quite often, manufacturers manage very well equipped testing laboratories or premises and their competence is sometimes higher than the abilities of certain notified bodies. Therefore the reliability of the tests and the level of safety could be even improved in this way. However, in this case the in-house body must be accredited. By allowing in-house assessment, the costs in administration and double testing would be reduced, which should result in reductions of the final price for users and consumers. It is necessary to stress that a specific sectoral legislative instrument remains free to require the use of an accredited third party where this is felt necessary (art 4.5.c of the Decision).

## 5.7 Module C2 (Conformity to type based on internal production control plus supervised product checks at random intervals)

Module C2 is a variant of module C and covers only the production phase, in a similar way module A2 is variant of module A. Under modules C/C1/C2 the conformity is evaluated against an approved EC-type resulted under module B (this notion does not exist under modules A/A1/A2 and variants as they cover both design and production phase)

Similar to modules A/A2, module C2 in comparison to module C provides for additional provisions containing the following supplementary requirements: at the choice of the manufacturer, either an accredited in-house body (first-party conformity assessment) or a notified body (third-party conformity assessment), chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the product, taking into account inter alia the technological complexity of the products and the quantity of production.

An adequate sample of the final products, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product performs within acceptable limits, with a view to ensuring conformity of the product. According to art 4.6.a of the Decision, the legislative instrument must specify the appropriate tests, the adequate sampling schemes, the operational characteristics of the statistical method to be applied and the corresponding action to be taken by the notified body and/or the manufacturer

The term “acceptable” is used because a random sampling is a semi-statistical method and consists in picking up and testing samples and thus may perform only in acceptable limits.

Module C2 lays down an additional option for the legislator: the use of an accredited in-house body. Thus, the manufacturer could either carry out tests and product checks through and under the responsibility of a third-party (notified body chosen by the manufacturer), as is done currently, or to implement them by an accredited body that forms a part of manufacturer’s organisation.

The reason is that quite often, manufacturers manage very well equipped testing laboratories or premises and their competence is sometimes higher than the abilities of certain notified bodies. Therefore the reliability of the tests and the level of safety could be even improved in this way. However, in this case the in-house body must be accredited. By allowing in-house assessment, the costs in administration and double testing would be reduced, which should result in reductions of the final price for users and consumers. It is necessary to stress that a specific sectoral legislative instrument remains free to require the use of an accredited third party where this is felt necessary (art 4.5.c of the Decision).

## 5.8 Module D (Conformity to type based on quality assurance of the production process)

Module D covers only the production phase and follows module B.

The manufacturer operates an approved quality system for the control of the production process (manufacturing part and inspection of final product). The notified body (third-party conformity assessment) assesses the quality system in order to determine that this system ensures that the products are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the legislative instrument that apply to them. Upon positive assessment, it is up to the manufacturer to ensure and declare on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

If the manufacturers' quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module.

Remark: initially Module D was based on the old EN ISO 9002:1994[4] which has been incorporated later into EN ISO 9001

[4] Quality systems - Model for quality assurance in production, installation and servicing

## 5.9 Module D1 (Quality assurance of the production process)

Module D1 is a variant of module D and covers both design and production phase; it concentrates however on the production phase:

Module D1 provides for the possibility of using the advantages of module D without the necessity of recurring to type examination (module B) in the design phase. In the case of products of simple design and construction, which do not represent a high risk, the use of manufacturer's declaration of conformity with the essential requirements, instead of an EC-type examination, reduces also burdens on manufactures as well as costs. Thus, the main focus of D1 is on the production phase.

Module D1 in comparison to module D provides for additional provisions containing the supplementary requirement that the manufacturer must draw up the technical documentation of the product. As under module D1 there is no approved EC-type (no module B preceded), it is necessary to draw up here the technical documentation.

Similar to module D, the manufacturer operates an approved quality system for the control of the production process (manufacturing part and inspection of final product). The notified body (third-party conformity assessment) assesses the quality system in order to determine that this system ensures that the products are in conformity with ensure compliance of the products with the requirements of the legislative instrument that apply to them (and not to an EC-type as it is the case under module D). Upon positive assessment, it is up to the manufacturer to ensure and declare on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them

If the manufacturers quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module.

Remark: initially Module D1 was based on the old EN ISO 9002:1994[5] which has been incorporated later into EN ISO 9001

[5] Quality systems - Model for quality assurance in production, installation and servicing

## 5.10 Module E (Conformity to type based on product quality assurance)

Module E covers only the production phase and follows module B.

The manufacturer operates an approved quality system for the control of the final product inspection and testing. The notified body (third-party conformity assessment) assesses the quality system in order to determine that this system ensures that the products are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the legislative instrument that apply to them. Upon positive assessment, it is up to the manufacturer to ensure and declare on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

The idea behind module E is similar to the one under module D: both are based on a quality system and follow module B. Their difference is that the quality system under module E aims to ensure the quality of the final product, while the quality system under module D (and D1 also) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E is similar to module D without the provisions relating to the manufacturing process

If the manufacturers quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module.

Remark: initially Module E was based on the old EN ISO 9003:1994[6] which has been incorporated later into EN ISO 9001

[6] Model for quality assurance in final inspection and test

## 5.11 Module E1 (Quality assurance of final product inspection and testing)

Module E1 is a variant of module E and covers both design and production phase; it concentrates however on the production phase:

Module E1 provides for the possibility of using the advantages of module E without the necessity of recurring to type examination (module B) in the design phase (similar to module D1 vs. D). In the case of products of simple design and construction, which do not represent a high risk, the use of manufacturer's declaration of conformity with the essential requirements, instead of an EC-type examination, reduces also burdens on manufactures as well as costs. Thus, the main focus of E1 is on the production phase.

Module E1 in comparison to module E provides for additional provisions containing the supplementary requirement that the manufacturer must draw up the technical documentation of the product. As under module E1 there is no approved EC-type (no module B preceded), it is necessary to draw up here the technical documentation.

In module E1 similar to module E the manufacturer operates an approved quality system for the control of the final product inspection and testing. The notified body (third-party conformity assessment) assesses the quality system in order to determine that this system ensures that the products are in conformity with ensure compliance of the products with the requirements of the legislative instrument that apply to them (and not to an EC-type as it is the case under module E). Upon positive assessment, it is up to the manufacturer to ensure and declare on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them

The idea behind module E1 is similar to the one under module D1: both are based on a quality system and do not make use of any approved EC-type. Their difference is that the quality system under module E1 (and E also) aims to ensure the quality of the final product, while the quality system under module D1 (and D also) aims to ensure the quality of the whole production process (that includes the manufacturing part and the test of final product). E1 is similar to module D1 without the provisions relating to the manufacturing part

In fact there is analogy between modules D/D1 and E/E1. D, E make use of an EC-type, while D1, E1 do not. On the other hand D, D1 target the production process, while E, E1 target the final product

If the manufacturers quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module.

Remark: initially Module E1 was based on the old EN ISO 9003:1994[7] which has been incorporated later into EN ISO 9001

[7] Model for quality assurance in final inspection and test

## 5.12 Module F (Conformity to type based on product verification)

Module F covers only the production phase and follows module B

The main idea behind module F is that a notified body (third-party conformity assessment) chosen by the manufacturer carries out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EC-type examination certificate and with the applicable requirements of the legislative instrument.

The examinations and tests are carried out, at the choice of the manufacturer either by examination and testing of every product or by examination and testing of the products on a statistical basis. However, according to art 4.5.d of the Decision the legislator may specify this manufacturer's choice. Furthermore and according to art 4.6.a of the Decision, the legislator determines the products concerned, the appropriate tests, the adequate sampling schemes, the operational characteristics of the statistical method to be applied and the corresponding action to be taken by the notified body and/or the manufacturer

Module F is very close to module C (and its variants). Both F and C (and variants) are based on product checks in order to determine the conformity of the product to the approved EC-type. However, under module F it is the notified that checks completely this compliance and not the manufacturer as it is in C and its variants (in C1 the in-house or notified body checks only some aspects of the product, while in C2 it performs random checking)

At the end, it is again up to the manufacturer to ensure and declare on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them

Module F is not based on any quality assurance system.

## 5.13 Module F1 (Conformity based on product verification)

Module F1 is a variant of module F and covers both design and production phase; it concentrates however on the production phase.

Module F1 provides for the possibility of using the advantages of module F without the necessity of recurring to type examination (module B) in the design phase (similar to module D1 vs. D, E1 vs. E). In the case of products of simple design and construction, which do not represent a high risk, the use of manufacturer's declaration of conformity with the essential requirements, instead of an EC-type examination, reduces also burdens on manufactures as well as costs. Thus, the main focus of F1 is on the production phase.

The main idea behind module F1 is that a notified body (third-party conformity assessment) chosen by the manufacturer carries out appropriate examinations and tests in order to check the conformity of the products with the applicable requirements of the legislative instrument (and not to an EC-type as it is the case under module F).

The examinations and tests are carried out, at the choice of the manufacturer either by examination and testing of every product or by examination and testing of the products on a statistical basis. However, according to art 4.5.d of the Decision the legislator may specify this manufacturer's choice. Furthermore and according to art 4.6.a of the Decision, the legislator determines the products concerned, the appropriate tests, the adequate sampling schemes, the operational characteristics of the statistical method to be applied and the corresponding action to be taken by the notified body and/or the manufacturer

Module F1 in comparison to module F provides for additional provisions containing the supplementary requirement that the manufacturer must draw up the technical documentation of the product. As under module F1 there is no approved EC-type (no module B preceded), it is necessary to draw up here the technical documentation.

Module F1 is not based on any quality assurance system.

## 5.14 Module G (Conformity based on unit verification)

Module G covers both design and production phase

Here the main idea is that the notified body (third-party conformity assessment) examines *every individual product* and carries out the appropriate tests to ensure conformity with the relevant requirements of the directive. The notified body draws up a certificate of conformity concerning the tests carried out.

However the manufacturer must, prior to the intervention of notified body:

- carry out an adequate analysis and assessment of the risk(s).
- take all measures necessary so that the manufacturing process ensures compliance of the manufactured products with the legislative instruments that apply to them
- carry out detailed tests and controls
- monitor the compliance of the products

This module is appropriate to be used for highly complicated and customised products with a very low series volume (e.g. turbines, expensive instruments)

## 5.15 Module H (Conformity based on full quality assurance)

Module H covers both design and production phase.

The manufacturer operates an approved quality system for design, manufacture and final product inspection and testing of the products. The notified body (third-party conformity assessment) assesses the quality system in order to determine that this system ensures compliance of the products with the requirements of the legislative instrument that apply to them. Upon positive assessment, it is up to the manufacturer to ensure and declare on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

Module H goes well beyond D1 (and E1). D1 requires for the design phase only the establishment of technical documentation. H goes well beyond that: product design is an integral part of the quality system. In this respect the quality system required under module H provides not only for the production and final product inspection and testing (as the quality system in module D1 does) but also for the design specifications, control and verification techniques.

Under module H, there is no EC-type examination.

If the manufacturers quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module.

Remark: initially Module H was based on the old EN ISO 9001:1994[8] which has merged later with EN ISO 9002:1994 and EN ISO 9003: 1994 into the present EN ISO 9001[9]

[8] Quality systems - Model for quality assurance in design/development, production, installation and servicing

[9] Quality management systems — Requirements

## 5.16 Module H1 (Conformity based on full quality assurance plus design examination)

Module H1 is a variant of module H and covers both design and production phase

In the case of module H1, when the manufacturer operates a full quality assurance system, but the verification of the conformity of design and the issuance of EC design examination certificate by a notified body (third-party conformity assessment) is necessary, it is ensured that the manufacturer undergoes only once the control of the design phase and the production phase. That would not be the case of a combination of other seemingly appropriate modules or procedures, such as B+H, when the design phase would be evaluated twice. In both modules H, H1 product design is examined; however module H1 goes beyond H, as the design examination leads (upon positive assessment by the notified body) to the issuing of an EC-design examination certificate.

The EC-design examination certificate must not be confused with the EC-type examination certificate of module B that attests the conformity of a specimen "representative of the production envisaged", so that the conformity of the products may be checked against this specimen. Under EC design examination certificate of module H1, there is no such specimen. EC design examination certificate attests that the conformity of the design of the product has been checked and certified by a notified body so that the conformity of this product may be ensured by means of a full quality system operated by the manufacturer and approved by the notified body

Module H1 in comparison to module H provides for additional provisions containing the following supplementary requirements: the manufacturer must lodge a separate application for the examination of the product design with the same notified body that will assess the quality system

The notified body examines the manufacturer's technical design specifications including the standards that have been applied and the necessary supporting evidence of their adequacy, in particular if the relevant harmonised standards have not been applied. The supporting evidence must include the result of tests carried out by the appropriate laboratory of the manufacturer or on his behalf. The notified body issues an EC design examination certificate.

Furthermore similar to module H, under module H1 the manufacturer operates an approved quality system an approved quality system for design, manufacture and final product inspection and testing of the products. The notified body (third-party conformity assessment) assesses the quality system in order to determine that this system ensures compliance of the products with the requirements of the legislative instrument that apply to them. Upon positive assessment, it is up to the manufacturer to ensure and declare on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

If the manufacturers quality system conforms to EN ISO 9001 (supplemented if necessary to take into account the specific nature of the products for which it is implemented), it is presumed to fulfil the requirements of the module.

Remark: initially Module H1 was based on the old EN ISO 9001:1994[10] which has merged later with EN ISO 9002:1994 and EN ISO 9003: 1994 into the present EN ISO 9001[11]

[10] Quality systems - Model for quality assurance in design/development, production, installation and servicing

[11] Quality management systems — Requirements

**5.17 Overview**

| Modules | Phases covered | Description | Intervention of notified body in the production phase |
|---|---|---|---|
| A | Design + Production | The manufacturer ensures himself the conformity of the products to the legislative requirements (no EC-type). - Internal production control | No intervention<br>The manufacturer carries out himself all checks a notified body would do |
| A1 | Design + Production | A + tests on specific aspects of the product | Either notified body or in-house accredited body[12]: |
| A2 | Design + Production | A + product checks at random intervals | Either notified body or in-house accredited body[13]: |
| B | Design | EC-type examination | Module B covers only the design phase |
| C | Production (follows B) | Conformity to EC-type by means of internal production control. The manufacturer carries out himself all checks a notified body would do | No intervention<br>The manufacturer carries out himself all checks a notified body would do |
| C1 | Production (follows B) | C + tests on specific aspects of the product | Either notified body or in-house accredited body[14]: |
| C2 | Production (follows B) | C + product checks at random intervals | Either notified body or in-house accredited body[15]: |
| D | Production (follows B) | Production (manufacturing part and inspection of final product)quality assurance (based on ISO 9001) in order to ensure conformity to EC type | Notified Body |
| D1 | Design + Production | Production (manufacturing part and inspection of final product) quality assurance (based on ISO 9001) in order to ensure conformity to legislative requirements (without EC-type)<br>(used like D without module B) | Notified Body |
| E | Production (follows B) | Product quality (=production quality without the manufacturing part) assurance (based on ISO 9001) in order to ensure conformity to EC type<br>(like D without the manufacturing part) | Notified Body |

[12] The legislator may restrict manufacturer's choice

[13] The legislator may restrict manufacturer's choice

[14] The legislator may restrict manufacturer's choice

[15] The legislator may restrict manufacturer's choice

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| | | | |
|---|---|---|---|
| E1 | Design + Production | Product quality (=production quality without the manufacturing part) assurance (based on ISO 9001) in order to ensure conformity to legislative requirements (without EC-type)<br>(like D1 without the manufacturing part – used like E without module B) | Notified Body |
| F | Production (follows B) | Product examination (testing of every product or statistical) in order to ensure conformity to EC-type<br>(like C and variants but the notified body performs the whole part of product examinations in order to check the conformity to the EC-type) | Notified Body |
| F1 | Design + Production | Product examination (testing of every product or statistical) in order to ensure conformity to legislative requirements (without EC-type)<br>(used like F without module B) | Notified Body |
| G | Design + Production | Verification of every individual product ) in order to ensure conformity to legislative requirements (no EC-type) | Notified Body |
| H | Design + Production | Full quality assurance (based on ISO 9001) in order to ensure conformity to legislative requirements (no EC-type)<br>(like module D1 plus deeper examination of product design that is under H part of the quality assurance process) | Notified Body |
| H1 | Design + Production | Full quality assurance (based on ISO 9001) plus design examination in order to ensure conformity to legislative requirements (no EC-type but EC-design examination certificate)<br>(like module H with additionally the issuing of a EC design examination certificate) | Notified Body |

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