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Regulatory policy
Regulatory Approach for the free circulation of goods

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SUBJECT: DIFFERENCES BETWEEN CONFORMITY ASSESSMENT MODULES AS LAID DOWN IN NEW APPROACH (DECISION 93/465/EEC -OLD MODULES) AND AS LAID DOWN IN THE NEW LEGAL FRAMEWORK (DECISION 768/2008/EC -NEW MODULES)

1. Introduction

The intention of the new modules set 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. In an effort to make the system simpler, it could be tempting to try to reduce substantially the number of modules and provide a general model with, for example, 6 different modules (manufacturer's declaration, third-party assessment and quality assurance in both design and production phase). However, given the development already experienced, this model would inevitably lead to the necessity of specific sectors to adjust the simple modules to their particular needs, thus creating a high number of different ad hoc variants. Such system would be in the end less transparent than the proposed solution and more difficult to trace and manage.

In this respect, the New Legal Framework provides more variants within modules. The reason for providing more variants within modules (e.g. the old Aa options or the new A1 and A2 modules) is to ensure the necessary level of protection for products presenting higher level of risk, without imposing 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.

The sequences of the procedures were revised to obtain a better logical structure and the wording of the modules was corrected so as to be consistent. While the text of the proposal may appear to be significantly longer than the relevant parts of the modules decision, in reality it is only due to the fact that the text stipulates expressly the different modules in the whole length of the procedure, in full and in sufficient detail, thus avoiding uncertainty or confusion. The sectoral legislation in the future will be able to include the appropriate modules for each product category by direct reference to the relevant horizontal text. This avoids the need for each sectoral instrument to rewrite all the applicable modules and procedures itself and in a specific manner, thereby opening the most important possibility for changes, exceptions, adjustments etc.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: B100, 05/11. Telephone: direct line (32-2) 199 96 93. Fax: (32-2) 299 80 31

E-mail: zacharias.bilalis@ec.europa.eu

This approach is also in line with the overall objective of the horizontal proposal in preparation to be able to serve as a general framework for technical harmonisation, to which the various sectoral instruments would make direct reference. This appears to be the only way to ensure some kind of stability and coherence between the various sectoral texts over time. In the end, this will also allow the number of pages of the sectoral instruments to be reduced considerably and, therefore, contribute as a whole to the objective of simplification.

Furthermore by bringing more coherence into the system of modules and, therefore, across all sectoral directives it increases transparency, which is beneficial both for legislators and stakeholders. If applied properly by the legislator, the system should provide more flexibility and less burdensome procedures for the manufacturers. That would reduce the costs for all concerned, not only for manufacturers, but also for public authorities, including market surveillance authorities. The new set of modules responds to the needs of economic operators without lowering the required level of safety.

1. Main differences between old modules (as laid down in Decision 93/465/EEC) and new ones (as laid down in Decision 768/2008/EC of the New Legal Framework)

- The new modules A1 and A2 replace the two existing versions of the old module Aa which provides for additional provisions containing supplementary requirements. New modules C1 and C2 are intended to substitute the two options with possible supplementary requirements laid down in the old module C.

  The new modules A1, A2, C1 and C2 lay down an additional option for the legislator: the use of an accredited in-house body. In the mentioned modules, 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. Under modules A2, C2 product checks are carried out at random intervals

  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.

- Module B tackles the need for greater flexibility to be provided for, through the extension of the concept of type examination to include 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 and to recognise relevant practice where the examination of the complete specimen "representative of the production envisaged" is either not economically viable or not necessary, such as for well-known products applying standard technology. In this context, type examination may be carried out in three manners:

- either through examination of a specimen, representative of the production envisaged, of the complete product (production type as exists in old module B);

- or through assessment of the technical design of the product through examination of the technical documentation and supporting evidence plus examination of specimens for one or more critical parts of the product (combination of production type and design type –introduced in the new module B);

- or through assessment of the technical design of the product requiring the examination of the technical documentation and supporting evidence, without examination of a specimen (design type–introduced in the new module B).

The inclusion of the proposed design examination module in this way also avoids increasing further the number of modules and their variants

- The possibility of using modules D, E and F not in combination with module B, but on their own (for example, for certain products of simple design) was already given in the footnotes to old modules D, E and F – those options now become modules D1, E1 and F1.

  The new modules D1, E1 and F1 provide for the possibility of using the advantages of modules D, E and F respectively, without the necessity of recurring to type examination (module B) in the design phase. In the case of products of simple design, but complicated production/manufacturing, the examination of the technical documentation in order to check the design, instead of an EC-type examination, reduces also burdens on manufactures as well as costs.

- Module H1 supersede the supplementary option "design examination" that figures in old module H.

  In the case of the new 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 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-type examination certificate

- SMEs specificities are taken into account during the implementation of the new modules in relation to administrative burdens. In this respect recital (50) of the Decision states that, rather than providing for general exceptions and derogations for such enterprises, which might imply that they or their products are second-rate or sub-quality, Community sectoral legislation should provide for the characteristics of such enterprises to be taken into account:

  (a) in setting the rules for the selection and implementation of the most appropriate conformity-assessment procedures

  (b) concerning the obligations placed on conformity-assessment bodies to operate in a proportionate manner in relation to the size of undertakings.

Furthermore Art 4.4 of the Decision provides that for custom-made products and small series production, the technical and administrative conditions relating to conformity-assessment procedures shall be alleviated.

- Old modules require from the manufacturer to ensure and declare that the products concerned satisfy the requirements of the directive that apply to them. New modules require from the manufacturer to ensure and declare on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument (not only directive) that apply to them.

  Additionally new modules require explicitly that a copy of the declaration of conformity must be available to the relevant authorities upon request.

- Under new modules the authorised representative, if any, must be established within the EU.

  Some old modules state that where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market. With the new text this provision has become obsolete and been deleted as art R3.1, R1.4 of the Decision states that manufacturers may appoint, by a written mandate, any natural or legal person established within the Community, ("the authorised representative" – see its definition under art R1.4), to act on their behalf for specified tasks with regard to the obligations of manufacturers.

  For sake of legal certainty, new modules specify that the authorised representative may fulfil manufacturer's obligations, only if this is specified in the mandate. In modules where a quality system is required the role of the authorised representative is extended as he is allowed to lodge the application for the examination of the quality system.

- In the new modules, there is no reference to CE marking, so that they may be used also in areas where CE marking is nor foreseen. In this respect, new modules stipulate that the manufacturer must affix the required conformity marking set out in the legislative instrument.

- All footnotes in the old modules have been moved out and transferred to the text. These footnotes provided either for additional information that is an integral part of the text of the modules or instructions for the sectoral legislator that have their place at the main text of the Decision. This has been done for the sake of clarity and in order for the sectoral legislator to be able to make use of the new modules by just referring to them (this is made possible only if the text of the modules is "instructions-free") and without needing to copy them. More specifically:

  The text of the footnotes in the old modules referring to the content of the technical documentation has been for the sake of clarity reformulated and moved to the main text of the new modules. The new modules acknowledge the fact that technical specifications (published in the Official Journal of the EU) other than harmonised standards may be applied by the manufacturer. Thus term "harmonised standards" has been replaced by the term "harmonised standards and/or other relevant technical specifications published in the Official Journal of the EU". In case where these harmonised standards and/or other technical specifications have been partly applied,

the new text requires that technical documentation specifies the parts that have been applied.

The text of the footnotes of the old modules referring to the parameters of the modules the sectoral legislator may modify has been for the sake of clarity reformulated and moved under art. 4.5. Thus the legislator may:

(a)regarding technical documentation, require information additional to that which is already stipulated in the modules;

(b) regarding the time for which span that the manufacturer and/or notified body are obliged to keep any kind of documentation, alter the period stipulated in the modules;

(c) specify the manufacturer's choice as to whether , if the tests are carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer;

(d)where product verification is performed, specify the manufacturer's choice as to whether the examinations and tests to check the conformity of the products with the appropriate requirements will be carried out, either by examination and testing of every product, or by examination and testing of the products on a statistical basis;

(e) provide for the EC type examination certificate to have a period of validity;

(f) regarding the EC type examination certificate, specify relevant information for conformity-assessment and in service control to be included in the certificate or its annexes;

(g) provide for different arrangements regarding the obligations of the notified body to inform its notifying authorities;

(h) if the notified body carries out periodical audits, specify their frequency..

The text of the footnotes of the old modules referring to the provisions of the legislation that are necessary for the implementation of the modules has been for the sake of clarity reformulated and moved under art. 4.6. Thus the legislator must:

(a) where product checks and/or verification are performed, determine 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;

(b) where EC type examination is performed, determine the appropriate manner (design type, production type, design and production type) and the specimens required.

- An appeal procedure against decisions of the notified body was foreseen only in a part of the old modules. In the new text this provision, wherever existed (module B) has been moved under art 4.7, so that it applies to all modules.

- New modules defined the obligations of the manufacturer and the notified body more clearly than old ones. For example regarding notified bodies, new modules stipulate clearly:

  (a) the obligation of the auditing team to have knowledge of the applicable requirements of the legislative instrument

  (b) the information obligation of the body towards not only other bodies (as stipulated in the old modules) but also its notifying authorities.

Regarding manufacturers the new text clarifies their obligation to inform notified bodies of any change (not only update as in the old modules) in the quality system that may affect the conformity of the product.

Annex
Detailed analysis

Old Module A	**New Module A**
A1 states that the manufacturer ensures and declares that the products concerned satisfy the requirements of the directive that apply to them	A.1, A1.1, A2.1 state that the manufacturer ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.
A.1 states that the manufacturer draws up a written declaration of conformity	A.4.2, A1.5.2, A2.5.2 require that the manufacturer shall draw up a written declaration of conformity for a product model. The declaration of conformity shall identify the product for which it has been drawn up.
A.2 states that where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.	No need for such provision – Art R1.4, R3.1 of the decision state that manufacturers may appoint, by a written mandate, any natural or legal person established within the Community, ("the authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers
A.1 states that the manufacturer must affix the CE marking to each product	A.4.1, A1.5.1, A2.5.1 states that the manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument
A.1, A.2, A.4 state that instead the manufacturer its authorised representative may affix the CE marking, draw up a declaration of conformity and keep the documentation (technical documentation, copy of the declaration of conformity)	A.5 states that the manufacturer's obligations regarding conformity marking, keeping the documentation declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate
A.2 states that the manufacturer must keep the declaration of conformity for a period ending at least 10 years after the last product has been manufactured	A.4.2, A1.5.2, A.2.5.2 state that the manufacturer shall keep the declaration of conformity together with the technical documentation at the disposal of the national authorities for ten years after the product has been placed on the market
A.2.footnote2 states that the specific directives may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules
A.2.footnote3 states that the content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. For example, the documentation must contain so far as relevant for assessment:	A.2, A1.2, A2.2 state that the technical documentation shall contain, wherever applicable, at least the following elements:

- a general description of the product, - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product, - a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards have not been applied, - results of design calculations made, examinations carried out, etc., - test reports	- a general description of the product, -conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, - results of design calculations made, examinations carried out, etc., - test reports. Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules

Old Module Aa (additional to old module A)	New Modules A1, A2 (additional to new module A)
Both supervised product testing and supervised product checks at random intervals are tackled together by the old module Aa	Supervised product testing is tackled by new module A1 and supervised product checks at random intervals is tackled by new module A2
The possibility of using an in-house accredited body does not exist	A1.4, A2.4 allow the use of an in-house accredited body. Art 4.5.c states that the legislator may specify the manufacturer's choice as to whether , if the tests are carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer
Aa states that tests are carried out	A1.4 states that tests are carried out in order to verify conformity with the corresponding requirements of the legislative instrument A2.4 states that tests are carried out 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.
Aa does not specify how random intervals are defined	A2.4 states that random intervals are defined by the body
Aa states that product checking must include aspects such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc	Art 4.6.a states that the appropriate tests, the adequate sampling schemes and the corresponding action to be taken by the body and/or the manufacturer shall be defined by the specific legislative instrument.

Old Module B	**New Module B**
B.1 states that the notified body attest that a specimen meets the provision of the directive that apply to it	B.1 states that the attest that a specimen meets the provisions of the legislative instrument that apply to it
B.1 specifies that EC-type examination is done only by examining a specimen, representative of the production envisaged (production type examination) B.2 does not require that manufacturers application must include also supporting evidence for the adequacy of the technical design	B.2 extends of the concept of type examination to include two additional options: - assessment of the technical design of the product requiring the examination of the technical documentation and supporting evidence, without examination of a specimen (design type examination) - assessment of the technical design of the product through examination of technical documentation and supporting evidence plus examination of specimens for one or more critical parts of the product (combination of design- and product-type examination). In this respect, B.3 requires that manufacturers application must include also supporting a specimen representative and evidence for the adequacy of the technical design (not required in the old module B) Art 4.6.b specifies that where EC type examination is performed, the legislator must determine the appropriate manner (design type, production type, design and production type) and the specimens required.
B does not oblige explicitly the notified body to issue an evaluation report	B.5 obliges the notified body to issue an evaluation report (prior to its decision to issue or not the examination certificate to the manufacturer)
B.7 obliges the notified body to provide information other notified bodies	B.8 obliges the notified body to provide information other notified bodies and its notifying authorities
B does not oblige the notified body to keep itself appraised of any changes of the generally acknowledged state of the art which may indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument,	B.7 obliges the notified body to keep itself appraised of any changes of 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, and shall determine whether such changes require further investigations. If so, according to B.7 the notified body shall inform the manufacturer accordingly.
B.9 states that where neither the manufacturer nor his authorized representative is established within	No need for such provision – Art R1.4, R3.1 of the decision states that manufacturers may appoint, by a

the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.	written mandate, any natural or legal person established within the Community, ("the authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers
B.2 states that instead the manufacturer its authorised representative may lodge the application for the EC-type examination and keep the documentation (technical documentation, EC-type certificates)	B.10 (referring to B.7, B.9) states that the manufacturer's obligations regarding keeping the documentation and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate
B.5 states that provision must be made for an appeals procedure	Art 4.7 states that an appeal procedure against decisions of the notified body shall be available
B.6 states that the applicant must inform the notified body that holds the technical documentation concerning the EC type-examination certificate of all modifications to the approved product which must receive additional approval where such changes may affect the conformity with the essential requirements or the prescribed conditions for use of the product.	B.7 states that the manufacturer shall inform the notified body that holds the technical documentation relating to the EC-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential requirements of the legislative instrument or the conditions for validity of the certificate.
B.3.footnote6 states that the content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. For example, the documentation must contain so far as relevant for assessment: - a general description of the product, - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product, - a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards have not been applied, - results of design calculations made, examinations carried out, etc.,	B.3 states that the technical documentation shall contain, wherever applicable, at least the following elements: - a general description of the product, -conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, - results of design calculations made, examinations

- test reports	carried out, etc., - test reports. - a specimen representative and supporting evidence for the adequacy of the technical design (not required in the old module B). This supporting evidence shall mention any relevant documents that have been applied, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility. Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules
B.5.footnote7 states that the specific directives may provide for the certificate to have a period of validity	Art 4.5.e states that the legislator may provide for the EC type examination certificate to have a period of validity;
B does not tackle the issue of in-service control	Art 4.5.f states that regarding the EC type examination certificate, the legislator may specify relevant information for conformity-assessment and in service control to be included in the certificate or its annexes;
B.7.footnote8 states that the specific directives may provide for different arrangements regarding the obligations of the notified body to provide information	Art 4.5.g states that the legislator may provide for different arrangements regarding the obligations of the notified body to inform its notifying authorities;
B.9 states that the manufacturer must keep with the technical documentation copies of EC type-examination certificates and their additions for a period ending at least 10 years after the last product has been manufactured	B.9 states that the manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation for ten years after the product has been placed on the market
B.9.footnote9 states that the specific directives may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules

Old Module C	**New Modules C, C1, C2**
C.1 states that the manufacturer ensures and declares that the products concerned satisfy the requirements of the directive that apply to them	C.1, C1.1, C2.1 state that the manufacturer ensures and declares that the products concerned satisfy the requirements of the legislative instrument that apply to them.
C.1 states that the manufacturer draws up a written declaration of conformity	C.3.2, C1.4.2, C2.4.2 require that the manufacturer shall draw up a written declaration of conformity for a product model. The declaration of conformity shall identify the product model for which it has been drawn up.
Old module C tackles not only the case where no supervised testing/checks are performed but also both cases where supervised product testing and supervised product checks at random intervals are performed.	The case where no supervised testing/checks are performed is tackled by the new module C. Supervised product testing is tackled by new module C1 and supervised product checks at random intervals is tackled by new module C2
The possibility of using an in-house accredited body does not exist	C1.3, C2.3 allow the use of an in-house accredited body. Art 4.5.c states that the legislator may specify the manufacturer's choice as to whether , if the tests are carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer
C.3 states that tests are carried out	C1.3 states that tests are carried out in order to verify conformity with the corresponding requirements of the legislative instrument C2.3 states that tests are carried out 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.
C does not specify how random intervals are defined	C2.3 states that random intervals are defined by the body
C.3 states that product checking must include aspects such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc	Art 4.6.a states that the appropriate tests, the adequate sampling schemes and the corresponding action to be taken by the body and/or the manufacturer shall be defined by the specific legislative instrument
C.3 states that where neither the manufacturer nor his authorized representative is established within the Community, the obligation to keep the technical documentation available is the responsibility of the person who places the product on the Community market.	No need for such provision – Art R1.4, R3.1 of the decision states that manufacturers may appoint, by a written mandate, any natural or legal person established within the Community, ("the authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers

C.1 states that the manufacturer must affix the CE marking to each product	C.3.1, C1.4.1, C2.4.1 state that the manufacturer shall affix the required conformity marking as set out in the legislative instrument to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument
C1, C.3 state that instead the manufacturer its authorised representative may affix the CE marking, draw up a declaration of conformity and keep the documentation (technical documentation, copy of the declaration of conformity)	C.4, C1.5, C2.5 state that the manufacturer's obligations regarding conformity marking, documentation declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate
C.3 states that the manufacturer or his authorized representative must keep a copy of the declaration of conformity for a period ending at least 10 years after the last product has been manufactured	C.3.2, C1.4.2, C2.4.2 state that the manufacturer shall draw up a written declaration of conformity for a product model and keep it at the disposal of the national authorities for a period of ten years after the product has been placed on the market
C.3.footnote10 states that the specific directives may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules

Old Module D	**New Modules D, D1**
D.1 states that the manufacturer ensures and declares that the products concerned satisfy the requirements of the directive that apply to them	D.1, D1.1 state that the manufacturer ensures and declares that the products concerned satisfy the requirements of the legislative instrument that apply to them.
When D is used without module B, then according to footnote 12, A.2, A.3 (both concern technical documentation) must be added between points D.1 and D.2 in order to incorporate the need for technical documentation A.2, A3 state that the content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. For example, the documentation must contain so far as relevant for assessment: - a general description of the product, - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product, - a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards have not been applied, - results of design calculations made, examinations carried out, etc., - test reports	This option became now module D1. D1.2, D1.3 (both concern technical documentation) provide for the possibility of using the advantages of the new module D without the necessity of recurring to type examination (module B) in the design phase. D1.2 states that the technical documentation shall contain, wherever applicable, at least the following elements: - a general description of the product, -conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, - results of design calculations made, examinations carried out, etc., - test reports. Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules
D.3.1 states that he application of the	D3.1, D1.5.1 state that he application of the manufacturer must include:

manufacturer must include: - all relevant information for the product category envisaged, - the documentation concerning the quality system, - if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.	- the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition (not required explicitly by the old module D); – a written declaration that the same application has not been lodged with any other notified body (not required by the old module D); – all relevant information for the product category envisaged (required by the old module D also); – the documentation concerning the quality system (required by the old module D also); – the technical documentation of the approved type and a copy of the EC-type examination certificate in case of new module D (required by the old module D also) or the technical documentation for the design, manufacture and operation of the product in case of new module D1 (see D1.2 - not existed in the old module D) .
D.3.2 states that the quality system documentation must permit a a common understanding of the quality programmes, plan, manuals and records.	D.3.2 and D1.5.2 state that the quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.
D.3.3 states that the auditing team must have at least one member with experience of evaluation in the product technology concerned.	D.3.3, D1.5.3 state that in addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. D.3.3, D1.5.3 state also that the auditing team shall review the technical documentation
D.3.3 states that the notified body presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard	D.3.3., D1.5.3 state that the notified body shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.
D.1 states that the manufacturer draws up a written declaration of conformity	D.5.2, D1.7.2 require that the manufacturer shall draw up a written declaration of conformity for a product model. The declaration of conformity shall identify the product model for which it has been drawn up.
D.6 states that each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn	D.7, D1.9 state that each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued.

	D.7, D1.9 state also that each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted
D.1 states that the manufacturer must affix the CE marking to each product. The same article states that the CE marking (affixed by the manufacturer) must be accompanied by the identification symbol of the notified body	D.5.1, states that the manufacturer shall affix the required conformity marking set out in the legislative instrument and, under the responsibility of the notified body the latter's identification number to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument. D1.7.1 states that the manufacturer shall affix the required conformity marking and, under the responsibility of the notified body the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument (no EC-type under D1).
D.1, D3.4 state that instead the manufacturer its authorised representative may affix the CE marking, draw up a declaration of conformity and keep the notified body informed about updates in the quality system	D.8, D1.10, state that the manufacturer's obligations regarding conformity marking, keeping the documentation declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate D.8, D1.10 extend also the role authorised representative by allowing him to lodge the application for the examination of the quality system,.
D.3.4 states that the manufacturer shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.	D.3.5, D1.5.5 state that the manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.
D.4.3.footnote14 stets that n the specific directives, the frequency of the audits may be specified.	Art 4.5.h states that if the notified body carries out periodical audits, the legislator may specify their frequency..
D.5 states that the manufacturer must, keep all relevant documentation for a period ending at least 10 years after the last product has been manufactured	D.5.2, D.6, D1.7.2, D1.8 state that the manufacturer must keep the declaration of conformity and the documentation for a period ending at least ten years after the product has been placed on the market

D.5.footnote15. states that the specific directives may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules
D.6.footnote16 states that the specific directives may provide for different arrangements regarding the obligations of the notified body to provide information	Art 4.5.g states that the legislator may provide for different arrangements regarding the obligations of the notified body to inform its notifying authorities;

Old Module E	**New Modules E, E1**
E.1 states that the manufacturer ensures and declares that the products concerned satisfy the requirements of the directive that apply to them	E.1, E1.1 state that the manufacturer ensures and declares that the products concerned satisfy the requirements of the legislative instrument that apply to them.
When E is used without module B, then according to footnote 17, A.2, A.3 (both concern technical documentation) must be added between points E.1 and E.2 in order to incorporate the need for technical documentation	This option became now module E1. E1.2, E1.3 (both concern technical documentation) provide for the possibility of using the advantages of the new module E without the necessity of recurring to type examination (module B) in the design phase.
A.2, A3 state that the content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. For example, the documentation must contain so far as relevant for assessment:	E1.2 states that the technical documentation shall contain, wherever applicable, at least the following elements:
- a general description of the product,	- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,	-conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,	- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards have not been applied,	- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., - test reports	- results of design calculations made, examinations carried out, etc., - test reports.
	Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules

E.3.1 states that he application of the manufacturer must include: - all relevant information for the product category envisaged, - the documentation concerning the quality system, - if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.	E3.1, E1.5.1 state that he application of the manufacturer must include: - the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition (not required explicitly by the old module E); – a written declaration that the same application has not been lodged with any other notified body (not required by the old module E); – all relevant information for the product category envisaged (required by the old module E also); – the documentation concerning the quality system (required by the old module E also); – the technical documentation of the approved type and a copy of the EC-type examination certificate in case of new module E (required by the old module E also)or the technical documentation for the design, manufacture and operation of the product in case of new module E1 (see E1.2 - not existed in the old module E) .
E.3.2 states that the quality system documentation must permit a common understanding of the quality programmes, plan, manuals and records.	E.3.2 and E1.5.2 state that the quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.
E.3.3 states that the auditing team must have at least one member with experience of evaluation in the product technology concerned.	E.3.3, E1.5.3 state that in addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. E.3.3, E1.5.3 state also that the auditing team shall review the technical documentation
E.3.3 states that the notified body presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard	E.3.3., E1.5.3 state that the notified body shall presume conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specifications.
E.1 states that the manufacturer draws up a written declaration of conformity	E.5.2, E1.7.2 require that the manufacturer shall draw up a written declaration of conformity for a product model. The declaration of conformity shall identify the product model for which it has been drawn up
E.6 states that each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued	E.7, E1.9 state that each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it

and withdrawn	has issued. E.7, E1.9 state also that each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted
E.1 states that the manufacturer must affix the CE marking to each product. The same article states that the CE marking (affixed by the manufacturer) must be accompanied by the identification symbol of the notified body	E.5.1, states that the manufacturer shall affix the required conformity marking set out in the legislative instrument and, under the responsibility of the notified body the latter's identification number to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument. E1.7.1 states that the manufacturer shall affix the required conformity marking and, under the responsibility of the notified body the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument (no EC-type under E1).
E.1, E.3.4 state that instead the manufacturer its authorised representative may affix the CE marking, draw up a declaration of conformity and keep the notified body informed about updates in the quality system	E.8, E1.10, state that the manufacturer's obligations regarding conformity marking, keeping the documentation, declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate E.8, E1.10 extend also the role authorised representative by allowing him to lodge the application for the examination of the quality system,.
E.3.4 states that the manufacturer shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.	E.3.5, E1.5.5 state that the manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system.
E.4.3.footnote19 stets that n the specific directives, the frequency of the audits may be specified.	Art 4.5.h states that if the notified body carries out periodical audits, the legislator may specify their frequency.
E.5 states that the manufacturer must, keep all relevant documentation for a period ending at least 10 years after the last product has been manufactured	E.5.2, E.6, E1.7.2, E1.8 state that the manufacturer must keep the declaration of conformity and the documentation for a period ending at least ten years after the product has been placed on the market
E.5.footnote20. states that the specific directives	Art 4.5.b states that regarding the time the

may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules
E.6.footnote21 states that the specific directives may provide for different arrangements regarding the obligations of the notified body to provide information	Art 4.5.g states that the legislator may provide for different arrangements regarding the obligations of the notified body to inform its notifying authorities;

Old Module F	**New Modules F, F1**
F.1 states that the manufacturer ensures and declares that the products satisfy the requirements of the directive that apply to them	F.1, F1.1 state that the manufacturer ensures and declares that the products satisfy the requirements of the legislative instrument that apply to them.
When F is used without module B, then according to footnote 22, A.2, A.3 (both concern technical documentation) must be added between points F.1 and F.2 in order to incorporate the need for technical documentation	This option became now module F1. F1.2 (technical documentation), F1.3 (manufacturing) provide for the possibility of using the advantages of the new module F without the necessity of recurring to type examination (module B) in the design phase.
A.2, A3 state that the content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. For example, the documentation must contain so far as relevant for assessment:	F1.2 states that the technical documentation shall contain, wherever applicable, at least the following elements:
- a general description of the product,	- a general description of the product,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,	-conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product,	- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards have not been applied,	- a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc.,	- results of design calculations made, examinations carried out, etc.,
- test reports	- test reports.
	Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules

F.4.1 (testing of every product), F.5.2 (statistical verification) states that all products must be examined and appropriate tests must be done as set out in the relevant standard(s)	F.4.1(testing of every product), F1.5.1(testing of every product), F.5.2(statistical verification), F1.6.2 (statistical verification) state that all products shall be examined and appropriate tests must be done, as set out in the relevant harmonised standards and/or technical specifications. The above articles state also that in the absence of harmonised standards, the notified body decides on the appropriate tests to be carried out
F.4.2 (testing of every product) states that the notified body must affix or cause to be affixed, its identification symbol to each approved product F.5.4 (statistical verification) states that the manufacturer may, under the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.	F.4.2 (testing of every product), F1.5.2 (testing of every product), state that the notified body shall affix its identification number to each approved product or have it affixed under its responsibility. F.6.1, F.7 (both testing of every product and statistical verification), F1.7.1, F1.8 (both testing of every product and statistical verification) state that, the manufacturer may affix the notified body's identification number to the products, under the responsibility of the notified body (also during the manufacturing process if agreed by the notified body).
F.2 states that the manufacturer draws up a written declaration of conformity	F.6.2, F1.7.2 require that the manufacturer shall draw up a written declaration of conformity for a product model. The declaration of conformity shall identify the product model for which it has been drawn up.
F.2 states that the manufacturer shall affix the CE marking to each product	F.6.1, states that the manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that is in conformity with the type as described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument. F1.7.1 states that the manufacturer shall affix the required conformity marking to each individual product that satisfies the applicable requirements of the legislative instrument (no EC-type under F1).
F.3a, F.4.3 (testing of every product), F5.5 (statistical verification) state that instead the manufacturer its authorised representative may keep the certificate/declaration of conformity. According to F.2, only the manufacturer shall affix the CE marking and draw up a declaration of conformity	F.8, F1.9 state that the manufacturer's obligations regarding conformity marking, keeping the documentation declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate F.8, F1.9 extend also the role authorised representative by allowing him to affix the required conformity marking.

F.3.footnote23 states that the manufacturer's discretion may be limited in the specific directives as to whether the examinations and tests to check the conformity of the products with the appropriate requirements will be carried out, either by examination and testing of every product, or by examination and testing of the products on a statistical basis	Art 4.5.d states that where product verification is performed, the legislator may specify the manufacturer's choice as to whether the examinations and tests to check the conformity of the products with the appropriate requirements will be carried out, either by examination and testing of every product, or by examination and testing of the products on a statistical basis
F.3a states that the manufacturer must keep the declaration of conformity for a period ending at least 10 years after the last product has been manufactured	F.6.2, F1.7.2 state that the manufacturer must keep the declaration of conformity for a period ending at least 10 years after the product has been placed on the market F1.2 states that that the manufacturer shall keep the technical documentation for ten years after the product has been placed on the market
F.3a.footnote24. states that the specific directives may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules

Old Module G	**New Module G**
G.1 states that the manufacturer ensures and declares that the product conforms to the requirements of the directive that apply	G.1 states that the manufacturer ensures and declares that the product conforms to the requirements of the legislative instrument that apply
G.1 states that manufacturer draws up a written declaration of conformity	G.5.2 requires that the manufacturer shall draw up a written declaration of conformity for a product. The declaration of conformity shall identify the product for which it has been drawn up
There are no provisions regarding manufacturer's obligation to take all measures necessary in order that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the legislative instrument.	G.3 obliges the manufacturer to take all measures necessary to ensure that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the legislative instrument.
There is no clear obligation of the manufacturer to keep any documentation (technical documentation or copy of the declaration of conformity)	G.2, G.4, G.5.2 oblige the manufacturer to keep the technical documentation, the certificate of conformity and the copy of the declaration of conformity at the disposal of the relevant national authorities for a period of 10 years after the product has been placed on the market. Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules
G.2 states that the notified body affixes or causes to be affixed its identification number on the approved product	G.4, G.5.1 state that the notified body shall affix its identification number to the approved product, or have it affixed under its responsibility by the manufacturer (also during the verification process if ageed by the notified body)
G.2 states that all products must be examined and appropriate tests must be done as set out in the relevant standard(s)	G.4 states that products shall be examined and appropriate tests must be done, as set out in the relevant harmonised standards and/or technical specifications. G.4 states also that in the absence of harmonised standards and/or technical specifications, the notified body decides on the appropriate tests to be carried out
G.1 states that the manufacturer must affix the CE marking to the product	G.5.1, states that the manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual product that satisfies the applicable requirements of the legislative instrument.

G.1 states that instead the manufacturer its authorised representative may affix the CE marking and draw up a declaration of conformity	G.6 states that the manufacturer's obligations regarding conformity marking, keeping the documentation, declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate G.6 extends the role authorised representative by allowing him to establish and keep the technical documentation..
G.3.footnote25 states that the content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. For example, the documentation must contain so far as relevant for assessment: - a general description of the product, - conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the product, - a list of the standards, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards have not been applied, - results of design calculations made, examinations carried out, etc., - test reports	G.2 states that the technical documentation shall contain, wherever applicable, at least the following elements: - a general description of the product, -conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied, - results of design calculations made, examinations carried out, etc., - test reports. Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules

Old Module H	**New Modules H, H1**
H.1 states that the manufacturer ensures and declares that the products concerned satisfy the requirements of the directive that apply to them	H.1, H1.1 state that the manufacturer ensures and declares that the products concerned satisfy the requirements of the legislative instrument that apply to them.
H.3.1 states that he application of the manufacturer for the assessment of his quality system must include: - all relevant information for the product category envisaged, - the documentation concerning the quality system,	H3.1, H1.3.1 state that he application of the manufacturer for the assessment of his quality system must include: - the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition (not required explicitly by the old module H); – a written declaration that the same application has not been lodged with any other notified body (not required by the old module H); – the technical documentation as described in the legislative instrument, for one model of each category of products intended to be manufactured in case of H or all relevant information for the product category envisaged in case of H1 (the latter is required by the old module H also); – the documentation concerning the quality system (required by the old module H also);
H does not provide instructions regarding the content of the technical documentation	H.3.1, H1.4.2 state that states that the technical documentation shall contain, wherever applicable, at least the following elements: - a general description of the product, -conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., - descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product, - a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the Official Journal of the European Union, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised

	standards, the technical documentation shall specify the parts which have been applied, - results of design calculations made, examinations carried out, etc., - test reports. - (only for H1) the supporting evidence for the adequacy of the technical design. That evidence shall mention any documents that have been applied, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full, and shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility Art 4.5.a states that regarding technical documentation, the legislator may require information additional to that which is already stipulated in the modules *Note: under H1 technical documentation of the product is required already for the EC-type examination, while under H technical documentation of the product is required for the assessment of quality system*
H.3.3 states that the notified body presumes compliance with these requirements in respect of quality systems that implement the relevant harmonized standard	H.3.3, H1.3.3 states that the notified body presumes conformity with these requirements in respect of the elements of the quality system that comply with the corresponding specifications of the national standard that implements the relevant harmonised standard and/or technical specification.
H.3.3 states that the auditing team must have at least one member with experience of evaluation in the product technology concerned.	H.3.3, H1.3.3 state that in addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. H3.3 states also that the auditing team shall review the technical documentation. Under H1 an examination of the documentation is part of design verification (H1.4)
H.1 states that manufacturer draws up a written declaration of conformity	H.5.2, H1.6.2 require that the manufacturer shall draw up a written declaration of conformity for a product model. The declaration of conformity shall identify the product model for which it has been drawn up H1.6.2 states in addition that the declaration of conformity shall mention the number of the design examination certificate
H.1 states that the manufacturer must affix the CE	H.5.1, H1.6.1 state that the manufacturer shall affix the

marking to each product. H.1 states also that the CE marking (affixed by the manufacturer) must be accompanied by the identification symbol of the notified body	required conformity marking set out in the legislative instrument and, under the responsibility of the notified body the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.
H.1, H.3.4 state that instead the manufacturer its authorised representative may affix the CE marking, draw up a declaration of conformity and keep the notified body informed about updates in the quality system	H.8, H1.9 state that the manufacturer's obligations regarding conformity marking, documentation declaration of conformity and providing information may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate H.8, H1.9 extend also the role authorised representative by allowing him to lodge the application for the examination of the quality system and (only in H1.9) for the EC-type examination
H.3.4 states that the manufacturer shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.	H.3.5, H1.3.5 state that the manufacturer shall keep the notified body that has approved the quality system informed of any intended change of the quality system. H1.4.4 states that the manufacturer shall keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of the legislative instrument or the conditions for validity of the certificate.
Module H includes possible supplementary requirements regarding design examination.	This option became now module H1 (under H1.4 - design verification)
H.design_examination.2 states that the application of the manufacturer must include the technical design specifications, including standards, that have been applied, and the necessary supporting evidence for their adequacy,	H1.4.2 states that the application of the manufacturer for the examination of the design must include - the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address in addition (not required explicitly by the old module H); – a written declaration that the same application has not been lodged with any other notified body (not required by the old module H); - the technical documentation as described in the legislative instrument (not explicitly required by the old module H). – the supporting evidence for the adequacy of the technical design (required by the old module H).

H.design_examination.3 requires that the EC design examination certificate shall contain: - the conclusions of the examination, - conditions for its validity, - the necessary data for identification of the approved design and, if relevant, - a description of the product's functioning.	H1.4.3 requires that the EC design examination certificate and its annexes shall contain: - the name and address of the manufacturer, - the conclusions of the examination, - conditions (if any) for its validity - the necessary data for identification of the approved design, - all relevant information to allow the conformity of manufactured products to be evaluated with the examined design, and to allow for in-service control, where applicable.
H.design_examination does not stipulate explicitly what happens if the design does not satisfy the applicable requirements (such a provision exists in H.3.4 but only regarding the quality system)	H1.4.3 states that where the design does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue a design examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
H.design_examination does not oblige the notified body to keep itself appraised of any changes of the generally acknowledged state of the art which may indicate that the approved design may no longer comply with the applicable requirements of the legislative instrument,	H1.4.4 obliges the notified body to keep itself appraised of any changes of the generally acknowledged state of the art which indicate that the approved design may no longer comply with the applicable requirements of the legislative instrument and to inform the manufacturer
H.6, H.design_examination.5 oblige the notified body to provide information other notified bodies	H.7, H1.3.6 state that each notified body shall inform its notifying authorities of the quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of quality system approvals refused, suspended or otherwise restricted. H.7, H1.3.6 state each notified body shall inform the other notified bodies of the quality system approvals which it has refused, suspended or withdrawn, and, upon request, of the quality system approvals which it has issued. For the EC-type examination: H1.4.5 states that each notified body shall inform its notifying authorities about of the EC design examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise

	restricted. H1.4.5 states also that each notified body shall inform the other notified bodies about of the EC design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, about of the certificates and/or additions thereto which it has issued
H.4.3.footnote27 stets that n the specific directives, the frequency of the audits may be specified.	Art 4.5.h states that if the notified body carries out periodical audits, the legislator may specify their frequency..
H.5 states that the manufacturer must, keep all relevant documentation for a period ending at least 10 years <u>after the last product has been manufactured</u>	H.5.2, H.6, H1.6.2, H1.7 state that the manufacturer must keep the declaration of conformity and the documentation for a period ending at least ten years <u>after the product has been placed on the market</u> H1.4.5 (last paragraph) states that the notified shall keep a copy of the EC design examination certificate and the relevant documentation until the expiry of the validity of the certificate. H1.4.6 stipulates that the manufacturer shall keep a copy of the EC design examination certificate and the relevant documentation for 10 years after the product has been placed on the market
H.5.footnote28. states that the specific directives may alter period manufacturer and/or notified body are obliged to keep any kind of documentation	Art 4.5.b states that regarding the time the manufacturer and/or notified body are obliged to keep any kind of documentation, the legislator may alter the period stipulated in the modules
H.6.footnote29, H.design_examination.5.footonote30 state that the specific directives may provide for different arrangements regarding the obligations of the notified body to provide information	Art 4.5.g states that the legislator may provide for different arrangements regarding the obligations of the notified body to inform its notifying authorities;