L.N. 136 of 2003

PRODUCT SAFETY ACT
(ACT NO. V OF 2001)

Method for Designating Conformity Assessment Bodies Regulations, 2003

IN exercise of the powers conferred by articles 38 to 40 of the Product Safety Act, 2001, the Minister of Finance and Economic Affairs, on the advice of the Malta Standards Authority, has made the following regulations:–

Citation and commencement.

1.1. The title of these regulations is the Method for Designating Conformity Assessment Bodies Regulations, 2003.

1.2. These regulations shall become operative on the 1st July, 2003.

Definitions.

2.1. For the purposes of these regulations, all the definitions of the Act shall apply, and in addition:

2.1.1. "Authority" means the Malta Standards Authority as established by virtue of the Malta Standards Authority Act, Cap 419;

2.1.2. "the Decision" means Council Decision 93/465/EEC[1] concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives, reproduced as Schedule IV hereto;

2.1.3. "accreditation" means the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks;

Legal Notice 313 of 2001[2]: Malta Standards Authority (Establishment of the Accreditation Directorate) Order, 2001, lays

[1] OJ No. L 220, 30-08-93, P.23
[2] Published in the Government Gazette No. 17,177 of 20th December, 2001.

down the establishment, organisation and operation of the Accreditation Directorate within the Malta Standards Authority, acting as the only recognised National Accreditation Body in Malta.

2.1.4. "certification" means the process whereby a third party (Certification Body) provides written assurance that a product, operation or service conforms with the stipulated requirements;

2.1.5. "conformity" means the fulfilment by a product, process or service of specified requirements;

2.1.6. "conformity assessment" means any activity concerned with determining directly or indirectly that relevant requirements are fulfilled;

2.1.7. "conformity assessment body" is a body that conducts conformity assessment;

2.1.8. "conformity assessment procedure" means the procedure by which conformity assessment is attained;

2.1.9. "Directorate" means the Consumer and Industrial Goods Directorate of the Malta Standards Authority, established by virtue of L.N. 213 of 2000 - Malta Standards Authority (Establishment of Directorates) Order, 2000 - published in the Government Gazette No. 17,002 of 20th October, 2000.

2.1.10. "inspection" means the examination of a product design, product, service, process or plant, and the determination of their conformity with specific requirements or, on the basis of professional judgement, general requirements;

2.1.11. "inspection body" is a body that performs inspection;

2.1.12. "OJ" means the Official Journal of the European Union.

2.1.13. "Community" means the European Community.

2.1.14. "CE marking" means the CE conformity marking consisting of the symbol 'CE' as set out in Schedule IV to these regulations.

Scope.

3.1. These regulations set out the conditions for the recognition of the competence and the subsequent approval of bodies to carry out work on the certification and/or inspection of industrial products

pursuant to regulations issued under the Act, either to bring Maltese legislation in line with the European Union's New Approach Directives, or as national regulations governing the manufacture and control of industrial products.

3.2. These regulations shall regulate the method of designating conformity assessment bodies, the method of determining whether they fulfil the requirements and the method of withdrawing applicable decisions.

Confidentiality.

4.1 The Authority shall guarantee the confidentiality of data obtained on conformity assessment bodies.

4.1.1. The Directorate shall keep a register of conformity assessment bodies carrying out the tasks of conformity assessment on the basis of technical regulations.

4.1.2. This register shall be public and published by the Directorate in the most appropriate form.

CE Marking Directives and implementing regulations under the Act.

5.1. Maltese bodies wishing to operate within the scope of the "New Approach", CE Marking Directives, as implemented by virtue of the regulations listed in Schedule I to these regulations, shall follow the procedure listed in regulations 7.1 to 8.6 of these regulations.

5.2. Bodies in Member States of the Community wishing to operate in Malta within the scope of the "New Approach", CE Marking Directives shall:

5.2.1. be notified for this purpose by the Member State in which they have their registered office;

5.2.2. declare in writing to the Directorate that they intend to carry out the activity in question and that they agree to the terms of these regulations;

5.2.3. provide evidence of their notification.

National regulations.

6.1. Bodies in Malta and in Member States of the Community wishing to operate within the scope of national regulations that have been issued for purposes other than bringing Maltese legislation into line with European Union New Approach Directives, shall follow the procedure listed in regulations 7.1 to 8.6 of these regulations.

Designating Conformity Assessment Bodies.

7.1. The procedure for designating a conformity assessment body (hereinafter referred to as the "Applicant") shall commence with the submission of an application to perform conformity assessment tasks to the Directorate, in accordance with the general administrative procedure.

7.2. The application shall contain the following data, and the following evidence shall be enclosed:

7.2.1. general data (name or firm and address, legal status, organisational structure with a description of relations between individual organisational units, and data on the activities that could affect the impartiality of work);

7.2.2. document from a court register or from other register;

7.2.3. technical and staff capacities, and the locations of performance of conformity assessment tasks;

7.2.4. the technical regulation on the basis of which conformity assessment tasks are to be performed;

7.2.5. the definition of the type, area and scope of tasks and products to which the tasks refer;

7.2.6. the "Qualifications Dossier" drawn up according to Schedule II to these regulations and made up of:

7.2.6.1. the "Minimum Criteria Report" prepared by an Expert chosen by the Authority as per Schedule II (A) to these regulations; and

7.2.6.2. the "Accreditation Certificate" issued by the National Accreditation Body, or by another National Accreditation Body as recognised by the Authority, as per Schedule II (B) to these regulations.

7.3 The Directorate shall determine the applicant's qualifications on the basis of the documents submitted by the applicant in accordance with regulation 7.2 of these regulations.

7.3.1. After examining the submitted application, it shall assess whether it is necessary to make an assessment visit to the applicant's head office or any other locations where the activities relevant to the procedure are performed, or to obtain further evidence.

7.4. When the Applicant demonstrates its qualifications with the document referred to in regulation 7.2.6, the Directorate shall examine

the compliance of the scope of tasks relevant to the application with the scope of tasks for which the applicant has been accredited, or with the scope of tasks referred to in the qualifications report.

7.4.1. The costs of the provision of evidence on qualifications shall always be covered by the Applicant.

7.4.2. Should the Directorate determine that the submitted evidence of qualifications is incomplete and fails to demonstrate the fulfilment of all requirements under the relevant technical regulation, it may instruct the Applicant to complete them by the end of the procedure.

7.4.3. The Directorate shall regard the Applicant to be qualified if it has submitted a complete document referred to in regulation 7.2.6 of these regulations as defined by a relevant technical regulation. In this event, the Directorate shall issue an opinion communicated to the Minister who shall issue a decision on designation to perform particular tasks in conformity assessment procedures.

7.4.4. Should the scopes of tasks referred to in regulation 7.4 of these regulations fail to agree, the Directorate shall define the Applicant's scope of tasks which are not covered in the submitted documents, and shall instruct the Applicant to submit additional evidence, or shall adopt an opinion as to what type of additional evidence is needed. This opinion is communicated to the Minister who shall issue the relevant decision.

7.5. If the Applicant fails to submit the document referred to in regulation 7.2.6 of these regulations and is instructed by the Directorate to subsequently submit evidence on meeting the conditions for carrying out the tasks, the Directorate shall issue an opinion which is communicated to the Minister who shall adopt a decision on obtaining additional evidence.

7.6. On the basis of facts found out, the Directorate shall issue an opinion on:

(a) the Applicant's fulfilment of the conditions for the issuing and extension of the decision, and the opinion on the total or partial compliance of the document with the requirements of the relevant technical regulation in relation to regulation 7.2.6 of these regulations;

(b) the measures necessary for the elimination of deficiencies found out during the surveillance pursuant to the provisions of regulations 7.1 to 7.5 of these regulations;

(c) notification under regulation 8.1 of these regulations.

that shall be communicated to the Minister who shall issue a decision on the application.

7.7 The decision on designating a conformity assessment body shall contain at least the following data:

7.7.1. the title of the relevant technical regulation;

7.7.2. a detailed description of the scope of work determined in the decision for which qualifications have been found out;

7.7.3. period of validity of the decision;

7.7.4. identification number assigned to the conformity assessment body by the Minister;

7.7.5. name of signatory who has been empowered to sign on documents issued by the conformity assessment body.

7.8. A decision shall be issued to the conformity assessment body which has demonstrated its credentials by means of the "Qualifications Dossier" made up of a "Minimum Criteria Report" not older that three months, for a maximum of four years, and an "Accreditation Cerificate" for not longer than the duration of validity of the accreditation certificate.

7.9. The decision on designating the conformity assessment body may be extended after the expiry of the period of validity, or after the expiry of the validity of the documents referred to in regulation 7.8 above, if the applicant submits the valid evidence referred to in regulation 7.2 of these regulations.

7.10. The conformity assessment body may subcontract some clearly defined tasks to a subcontractor, if the sub-contractor can provide evidence that it meets the prescribed requirements referred to in regulation 7.2 of these regulations.

7.10.1. The subcontracted tasks shall supplement the activities carried out by the conformity assessment body, and shall form, with them, an indivisible whole.

7.10.2. The conformity assessment body shall be able to provide proof of the qualification of the sub-contractor, keep records thereof and assume total responsibility for the work executed by the sub-contractor.

7.10.3. The conformity assessment body shall keep a register of sub-contractors and the tasks granted to them.

Monitoring, Surveillance and Withdrawals.

8.1. The conformity assessment body shall permanently meet the requirements for designation, keep records of all procedures of conformity assessment for which it has been designated, and immediately notify the Directorate of any changes that could affect its qualification, the scope of activities from the decision or the fulfilment of the requirements for designation.

8.1.1. The conformity assessment body shall keep the records of all working tasks carried out and their results for at least ten years.

8.2. At the request of the Directorate, the conformity assessment body shall take part in qualification tests or other comparisons determined for conformity assessment bodies.

8.2.1. The conformity assessment body shall allow the Directorate access to all data related to the fulfilment of requirements for conformity assessment, and access to all premises where the tasks included in the scope of conformity assessment, as defined in the issued decision, are carried out.

8.3. Bodies carrying out industrial product certification or inspection work in accordance with the above provisions shall have their activities monitored in accordance with the provisions of Schedule III to these regulations.

8.4. The Directorate may carry out extraordinary surveillance of the conformity assessment body if the regularity of its actions is in doubt.

8.4.1. If necessary, it may involve the National Accreditation Body in the implementation of extraordinary surveillance.

8.5. Should the surveillance referred to in regulations 8.3 and 8.4 of these regulations found out that the conformity assessment body does not comply with the requirements for designation, the Directorate shall issue a decision determining measures and a deadline for the elimination of irregularities.

8.5.1. The conformity assessment body shall be obliged to notify the Directorate of the implementation of the measures determined in the decision by the set deadline.

8.5.2. Should the conformity assessment body fail to eliminate the determined irregularities by the set deadline, the Minister shall issue a decision on withdrawal and remove the name of that conformity assessment body from the register referred to in regulations 4.1.1 and 4.1.2 of these regulations.

8.6. The Minister shall also withdraw a decision in the event that the conformity assessment body notifies the Directorate that it wishes to cease performing the tasks referred to in that decision.

8.7. Manufacturers or producers of products falling within the scope of the provisions of regulation 3.1 of these regulations shall, in order to certify or inspect their products, in accordance with the provisions of the relevant regulations, make use of the bodies that appear on the list pubished in the register referred to in regulations 4.1.1 and 4.1.2 of these regulations.

Obligations.

9.1. The body in question shall, inter alia, co-operate with the competent authorities responsible for implementation of the regulations and contribute to the work of the relevant group of bodies meeting at national and/or European level.

9.2. For market surveillance work, which also includes the inspections carried out by the bodies, the latter shall:

9.2.1. send to the Directorate the Type Examination Certificates they issue or other testimonials issued further to the application of the regulations in question, as and when these are officially requested;

9.2.2. where possible, facilitate the work of the competent authorities during the conduct of sample checks.

Legal Proceedings.

10.1. In the event of its being established that a body, producer or manufacturer is engaged in activities that breach the terms of these regulations, Part IV of the Act is applicable and the granted authorisation shall be suspended or revoked or, if the body is a notified body from abroad, the authority responsible for notification will be informed.

10.1.1. In such cases, the name of the body shall be struck from the register provided for under regulations 4.1.1 and 4.1.2 of these regulations.

Notification.

11.1. The Minister shall inform the Commission and the other Member States of the designation and withdrawal of designation of conformity assessment bodies carrying out procedures under technical regulations which are subject to regulation 5.1 of these regulations.

Schedule I

IMPLEMENTATION OF THE "NEW APPROACH", CE MARKING DIRECTIVES IN MALTA

The implementation dates of the regulations published by the Ministry of Finance and Economic Affairs, acting on the advice of the Malta Standards Authority, are given in the table below. All current publications in the Government Gazette are available on the Malta Standards Autority website (www.msa.org.mt) as downloadable documents.

Published originally under the Quality Control (Exports, Imports and Local Goods) Act and kept in force by virtue of Article 41 of the new Product Safety Act, Cap. 427:

Legal Notice	Citation	Published	Coming into force
L.N. 16 of 1996	Safety of toys (88/378/EEC)	26th January 1996	1st July 1996
L.N. 52 of 1996	Appliances burning gaseous fuels (90/396/EEC)	18th March 1996	31st May 1996
L.N. 122 of 1998	Personal protective equipment (89/686/EEC)	8th May 1998	1st July 1998
L.N. 229 of 1998	Simple pressure vessels (87/404/EEC)	23rd October 1998	1st March 1998
L.N. 23 of 1999	Low voltage electrical equipment (73/23/EEC)	5th February 1999	1st March 1999
L.N. 24 of 1999	Electromagnetic compatibility (89/336/EEC)	5th February 1999	1st April 1999
L.N. 107 of 1999	Equipment and protective systems in potentially explosive atmospheres (94/9/EC)	22nd June 1999	1st January 2000

Published under the new Metrology Act, Act No: XXV of 2002:

L.N. 396 of 2002	Non-Automatic Weighing Instruments (90/384/EC)	31st December 2002	1st January 2004

Published following the enactment of the new Product Safety Act, Cap. 427, in March 2001:

Legal Notice	Citation	Published	Coming into force
L.N. 66 of 2001	Active implantable medical devices (90/385/EEC)	30th March 2001	1st April 2001
L.N. 231 of 2001	Recreational craft (94/25/EC)	28th September 2002	1st July 2002
L.N. 249 of 2001	Lifts (95/16/EC)	26th October 2001	1st July 2002
L.N. 250 of 2001	Machinery (98/37/EC)	26th October 2001	1st July 2002
L.N. 270 of 2001 as amended by L.N. 330 of 2002	Construction products (89/106/EEC)	2nd November 2001	1st July 2002
L.N. 329 of 2001	Radio equipment and telecommunications terminal equipment and mutual recognition of their conformity (1999/05/EC)	28th December 2001	1st January 2002
L.N. 61 of 2002	In-vitro diagnostic medical devices (98/79/EC)	12th March 2002	1st January 2003
L.N. 62 of 2002	New hot-water boilers fired with liquid or gaseous fuels (efficiency requirements) (92/42/EEC)	12th March 2002	1st January 2003
L.N. 63 of 2002	Energy efficiency requirements for household electric refrigerators, freezers and combinations thereof (96/57/EC)	12th March 2002	1st January 2003
L.N. 64 of 2002	Noise emission in the environment by equipment for use outdoors (2000/14/EC)	12th March 2002	1st January 2003
L.N. 248 of 2002	Pressure equipment (97/23/EC)	3rd September 2002	3rd September 2002
L.N. 331 of 2002	Transportable pressure equipment (1999/36/EC)	12th November 2002	1st January 2003
L.N. 332 of 2002	Interoperability of the trans-European high-speed rail system (96/48/EC)	12th November 2002	1st January 2003
L.N. 333 of 2002	Cableway installations designed to carry persons (2000/9/EC)	12th November 2002	1st January 2003
L.N. 334 of 2002	Interoperability of the trans-European conventional rail system (2001/16/EC)	12th November 2002	20th April 2003
L.N. 47 of 2003	Medical devices (93/42/EEC)	31st January 2003	31st January 2003

Schedule II

RECOGNITION OF TECHNICAL COMPETENCE

This Schedule sets out the framework and conditions for recognition of the technical competence of bodies, required under regulation 7.2.6 of these regulations, in carrying out industrial product certification and/or inspection work within the framework of the application of the regulatory provisions falling under the Act.

In all cases, responsibility for their approval lies with the Minister of Finance and Economic Affairs, acting on the advice of the Directorate.

Recognition of technical competence involves the preparation by the body concerned of a "Qualifications Dossier" for this purpose, composed of two documents, namely a "Minimum Criteria Report" issued by an Expert chosen by the Directorate and an "Accreditation Certificate" issued by the National Accreditation Body, or by another National Accreditation Body as recognised by the Authority:

A. CRITERIA TO BE TAKEN INTO ACCOUNT FOR THE EXPERT'S REPORT

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of the product which they inspect, nor the authorised representative of any of these parties. They shall not become either involved directly or as authorised representatives in the design, construction, marketing or maintenance of the product. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

2. The body and its staff shall carry out the verification tests with the highest degree of professional integrity and technical competence and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of the inspection, especially from persons or groups of persons with an interest in the result of verifications.

3. In addition to being technically competent, applicant bodies shall be legal persons under public law, legal persons under private law, private-sector bodies or associations of these, with a legal form of public or private limited companies, whose financial standing can be proved by means of the following supporting documents or records:

- Certificate of insurance and tax observance;
- Balance sheets for the last three years;
- Certificate stating that the body is not bankrupt, in liquidation, being wound up, in official receivership, in bankruptcy proceedings or in a similar situation arising from legal provisions;
- Certificate stating that the body is not in proceedings for bankruptcy, official receivership, creditor arrangements or other similar proceeding under legal provisions.

4. The body shall have at its disposal the necessary staff and possess the necessary facilities to enable it to perform properly the administrative and technical tasks connected with verification; it shall also have access to the equipment required for special verification.

5. The staff responsible for testing/inspection shall have:

   - sound technical and professional training,
   - knowledge of the Directive or regulations being applied,
   - satisfactory knowledge of the requirements of the tests they carry out and adequate experience of such tests,
   - knowledge of the technology used to manufacture the products to be checked, of the way they are used, of problems that may arise during their use and the likely consequences of these,
   - the ability to exercise professional judgment in respect of the conformity of the product with the requirements of the regulations being applied,
   - the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

6. In each instance, the body shall be in a position to assess the conformity of products against the essential requirements set out in the regulations and:

   - Where harmonised standards are used for conformity assessment, compliance with the essential requirements is assumed.
   - Where harmonised standards are not used for conformity assessment, or where standards do not specify a conformity assessment method, the body shall use its own method and be able to demonstrate that this method meets all the essential requirements for assessing the conformity of the product.

7. The impartiality of inspection staff shall be guaranteed. Their remuneration shall not depend on the number of tests carried out or on the results of such tests.

8. The body shall take out civil liability insurance for the services it provides and shall be able to justify the amount of this. This does not apply if its liability is

assumed by the Government of Malta in accordance with national law, or the Government of Malta itself is directly responsible for the tests.

9. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except *vis-à-vis* the competent administrative authorities) under a specific Directive or any provision of national regulations giving effect to it.

B. CRITERIA TO BE TAKEN INTO ACCOUNT FOR ACCREDITATION

1. Accreditation shall be based on the accreditation criteria defined in international standards, as applied by the National Accreditation Body, or by another National Accreditation Body as recognised by the Authority.

2. The applicant body shall specify:

   - The products or group of products whose conformity is to be assessed;
   - The standards used to evaluate product conformity, or the body's own method where standards are not used;
   - The conformity assessment procedures (modules) provided for in the Directive or law in question and selected for use.

   International standards as applied by the National Accreditation Body, or by another National Accreditation Body as recognised by the Authority, depend on the module applied by the body, as provided for in Council Decision 93/465/EEC, reproduced as Schedule IV to these regulations, or on the corresponding procedure provided for in the regulations in question.

3. During evaluation of the body to be accredited, account shall be taken of the following:

   - The guidelines for the application of the international standards issued by the EA (European Co-operation for Accreditation);
   - The Special Guidelines issued by the EA concerning additional requirements for Notified Bodies;
   - The documents from the European Commission's CERTIF series containing additional guidelines for the implementation of the Directives and on Notified Bodies.

4. After approval has been granted, bodies shall be subject to monitoring in order to ensure their consistent compliance with the above requirements, in accordance

with the regulations for Accredited Bodies as established by the National Accreditation Body, or by another National Accreditation Body as recognised by the Authority.

5. In Malta, accreditation certificates are issued by the National Accreditation Body, which was set up pursuant to Legal Notice 313 of 2001: Malta Standards Authority (Establishment of the Accreditation Directorate) Order, 2001, acting on the advise of the Accreditation Advisory Board. .

Schedule III

MONITORING OF BODIES

As part of the surveillance referred to in regulations 7.1 to 7.6 of these regulations, bodies shall be monitored by the Directorate, as follows:

1. Each year, at the end of each four-month period, the body sends to the Directorate a list of all the inspections or certifications it has carried out during the period in question.

2. The body sends to the Directorate the quality and procedural handbook and details of the inspections or certifications it carries out.

3. Monitoring includes:

   - A check of the documentation submitted pursuant to paragraph 2 above;
   - A sample check of manufacturers on whom inspections or certifications have been completed;
   - Completion of at least one site inspection or certification;
   - Evaluation of compliance with the obligations set out in paragraphs 1 and 2 of Schedule III to these regulations.

4. At any stage, the Directorate may involve the National Accreditation Body in drawing up the monitoring programme and during its execution.

Schedule IV

Council Decision 93/465/EEC

30. 8. 93 Official Journal of the European Communities No L 220/23

COUNCIL DECISION

of 22 July 1993

concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonization directives

(93/465/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,

Having regard to the proposal from the Commission [1],

In cooperation with the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

Whereas Council Decision 90/683/EEC of 13 December 1990 concerning the modules for the various phases of the conformity assessment procedures which are intended to be used in the technical harmonization directives [4] needs to be substantially amended in various places; whereas it is necessary, in a spirit of clarity and rationality, to consolidate its provisions by means of this Decision;

Whereas the Council adopted a Resolution on 21 December 1989 concerning a global approach to conformity assessments [5];

Whereas the introduction of harmonized methods for the assessment of conformity and the adoption of a common doctrine for their implementation are likely to facilitate the adoption of future technical harmonization directives concerning the placing on the market of industrial products and thus be conducive to the implementation of the internal market;

Whereas such methods should ensure that products are in full conformity with the essential requirements laid down in the technical harmonization directives, in order to provide, in particular, for the health and safety of users and consumers;

Whereas such conformity should be assured without imposing unnecessarily onerous conditions on manufacturers, and by means of clear and comprehensible procedures;

Whereas limited flexibility should be introduced as regards use of additional modules, or variations in the modules, when the specific circumstances of a particular sector or directive so warrant, but not to such a degree as to undercut the purpose of the current Decision and only when explicitly justified;

Whereas in the abovementioned Resolution of 21 December 1989 the Council approved as a guiding principle the adoption of common rules on the use of the CE marking;

Whereas in its Decision 90/683/EEC the Council laid down that the industrial products covered by the technical harmonization directives can be placed on the market only after the manufacturer has affixed the CE marking to them;

Whereas a single CE marking should be used in order to facilitate controls on the Community market by inspectors and to clarify the obligations of economic operators in respect of marking under the various Community regulations;

Whereas the aim of the CE marking is to symbolize the conformity of a product with the levels of protection of collective interests imposed by the total harmonization directives and to indicate that the economic operator has undergone all the evaluation procedures laid down by Community law in respect of his product,

HAS DECIDED AS FOLLOWS:

Article 1

1. The procedures for conformity assessment which are to be used in the technical harmonization directives relating to the marketing of industrial products will be chosen from among the modules listed in the Annex and in accordance with the criteria set out in this Decision and in the general guidelines in the Annex.

(1) OJ No C 160, 20. 6. 1991, p. 14; and OJ No C 28, 2. 2. 1993, p. 16.
(2) OJ No C 125, 18. 5. 1992, p. 178; OJ No C 115, 26. 4. 1993, p. 117; and Decision of 14 July 1993 (not yet published in the Official Journal).
(3) OJ No C 14, 20. 1. 1992, p. 15; and OJ No C 129, 10. 5. 1993, p. 3.
(4) OJ No L 380, 31. 12. 1990, p. 13.
(5) OJ NO C 10, 16. 1. 1990, p. 1.

These procedures may only depart from the modules when the specific circumstances of a particular sector or directive so warrant. Such departures from the modules must be limited in extent and must be explicitly justified in the relevant directive.

2. This Decision lays down rules for affixing the CE conformity marking provided for in Community legislation concerning the design, manufacture, placing on the market, entry into service or use of industrial products.

3. The Commission shall report periodically on the functioning of this Decision, and on whether conformity assessment and CE marking procedures are working satisfactorily or need to be modified.

No later than the end of the transitional period in 1997, or earlier if the matter is found to be urgent, the Commission shall also report back on any special problems raised by the incorporation of Council Directive 73/23/EEC of 19 February 1973 relating to electrical equipment designed for use within certain voltage limits [1] within the scope of CE marking procedures, and, in particular, whether safety is being compromised. It shall also review any problems raised by the issue of overlapping Council directives, and whether any further Community measures are required.

Article 2

1. Decision 90/683/EEC is hereby repealed.

2. References to the Decision repealed shall be construed as references to this Decision.

Done at Brussels, 22 July 1993.

For the Council

The President

M. OFFECIERS-VAN DE WIELE

ANNEX

CONFORMITY ASSESSMENT PROCEDURES AND CE MARKING IN THE TECHNICAL HARMONIZATION DIRECTIVES

I. GENERAL GUIDELINES

A. **The principal guidelines for the use of conformity assessment procedures in technical harmonization directives are the following:**

(a) the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to the health and safety of users and consumers;

(b) conformity assessment can be subdivided into modules which relate to the design phase of products and to their production phase;

(c) as a general rule a product should be subject to both phases before being able to be placed on the market if the results are positive (*);

(d) there are a variety of modules which cover the two phases in a variety of ways. The directives must set the range of possible choices which can be considered by the Council to give the public authorities the high level of safety they seek, for a given product or product sector;

(e) in setting the range of possible choices open to the manufacturer, the directives, will take into consideration, in particular, such issues as the appropriateness of the modules to the type of products, the nature of the risks involved, the economic infrastructures of the given sector (e.g. existence or non-existence of third parties), the types and importance of production, etc. The factors that have been taken into account must be explicitly spelled out by the Commission in these directives;

(f) the directives will, in setting the range of possible modules for a given product or product sector, attempt to leave as wide a choice to the manufacturer as is consistent with ensuring compliance with the requirements.

The directives will set out the criteria governing the conditions in which the manufacturer chooses the most appropriate modules for his production from the modules laid down by the directives;

(g) the directives should avoid imposing unnecessarily modules which would be too onerous relative to the objectives of the directive concerned;

(h) notified bodies should be encouraged to apply the modules without unnecessary burden for the economic operators. The Commission, in cooperation with the Member States, must ensure that close cooperation is organized between the notified bodies in order to ensure consistent technical application of the modules;

(i) in order to protect the manufacturers, the technical documentation provided to notified bodies has to be limited to that which is required solely for the purpose of assessment of conformity. Legal protection of confidential information is required;

(j) whenever directives provide the manufacturer with the possibility of using modules based on quality assurance techniques, the manufacturer must also be able to have recourse to a combination of modules not using quality assurance, and *vice versa*, except where compliance with the requirements laid down by the directives requires the exclusive application of a certain procedure;

(k) for the purposes of operating the modules, Member States must notify on their own responsibility bodies under their jurisdiction which they have chosen from the technically competent bodies complying with the requirements of the directives. This responsibility involves the obligation for the Member States to ensure that the notified bodies permanently have the technical qualifications required by the directives and that the latter keep their competent national authorities informed of the performance of their tasks. Where a Member State withdraws its notification of a body, it must take appropriate steps to ensure that the dossiers are processed by another notified body to ensure continuity;

(*) The specific directives may provide for different arrangements.

(l) in addition, with regard to conformity assessment, the sub-contracting of work shall be subject to certain conditions guaranteeing:

— the competence of the establishment operating as sub-contractor, on the basis of conformity with series EN 45 000 standards, and the capability of the Member State that has notified the sub-contracting body to ensure effective monitoring of such compliance,

— the ability of the body notified to exercise effective responsibility for the work carried out under sub-contract;

(m) notified bodies which can prove their conformity with harmonized standards (EN 45 000 series), by submitting an accreditation certificate or other documentary evidence, are presumed to conform to the requirements of the directives. Member States having notified bodies unable to prove their conformity with the harmonized standards (EN 45 000 series) may be requested to provide the Commission with the appropriate supporting documents on the basis of which notification was carried out;

(n) a list of notified bodies must be published by the Commission in the *Official Journal of the European Communities* and constantly updated.

B. The principal guidelines for the affixing and use of the CE marking are the following:

(a) The CE marking symbolizes conformity to all the obligations incumbent on manufacturers for the product by virtue of the Community directives providing for its affixing.

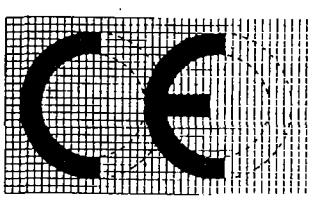
Thus, such conformity is not limited to the essential requirements relating to safety, public health, consumer protection, etc., as certain directives may impose specific obligations not necessarily forming part of the essential requirements.

(b) The CE marking affixed to industrial products symbolizes the fact that the natural or legal person having affixed or been responsible for the affixing of the said marking has verified that the product conforms to all the Community total harmonization provisions which apply to it and has been the subject of the appropriate conformity evaluation procedures.

(c) Where the industrial products are subject to other directives concerning other aspects and which also provide for the affixing of the CE marking, the latter must indicate that the products are also presumed to conform to the provisions of those other directives.

However, where one or more of these directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking indicates conformity to the provisions only of those directives applied by the manufacturer. In this case, particulars of the directives applied, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions accompanying the products or, where appropriate, on the data plate.

(d) 1. The CE conformity marking must consist of the initials 'CE' taking the following form:



If the CE marking is reduced or enlarged the proportions given in the above graduated drawing must be respected.

2. Where the directive concerned does not impose specific dimensions, the CE marking must have a height of at least 5 mm.

3. The CE marking must be affixed to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and to the accompanying documents, where the directive concerned provides for such documents.

4. The CE marking must be affixed visibly, legibly and indelibly.

(e) Any industrial product covered by the technical harmonization directives based on the principles of the global approach must bear the CE marking, save where the specific directives provide otherwise; such exceptions constitute derogations not from the marking requirement but from the administrative procedures for conformity evaluation, which may in certain cases be considered too cumbersome. Appropriate grounds must accordingly be given for any exception to or derogation from the marking requirement.

The CE marking is the only marking which certifies that the industrial products conform to the directives based on the principles of the global approach.

Member States must refrain from introducing into their national regulations any reference to a conformity marking other than the CE marking in connection with conformity to all the provisions contained in the directives on CE marking.

(f) The CE marking must be affixed at the end of the production control phase.

(g) The CE conformity marking must be followed by the identification number of the notified body within the meaning of paragraph I.A where the said body is involved in the production control phase within the meaning of this Decision.

Such identification numbers must be assigned by the Commission as part of the body notification procedure. The Commission must publish lists of the notified bodies in the *Official Journal of the European Communities;* such lists must be updated regularly.

A notified body must be assigned the same number when it is notified under several directives. The Commission must ensure that each notified body receives a single identification number, however many directives it is notified under.

(h) It is necessary to lay down provisions concerning the use of certain products. In this case, the CE marking and the identification number of the notified body may be followed by a pictogram or any other mark indicating, for example, the category of use.

(i) The affixing for any other marking liable to deceive third parties as to the meaning and form of the CE marking must be prohibited.

(j) A product may bear different marks, for example marks indicating conformity to national or European standards or with traditional optional directives, provided such marks are not liable to cause confusion with the CE marking.

Such marks may therefore only be affixed to the product, its packaging or the documentation accompanying the product on condition that the legibility and visibility of the CE marking are not thereby reduced.

(k) The CE marking must be affixed by the manufacturer or his agent established within the Community. In exceptional, duly warranted cases, the specific directives may provide that the CE marking can be affixed by the person responsible for placing the product on the Community market.

The identification number of the notified body must be affixed under its responsibility either by the body itself or by the manufacturer or his agent established within the Community.

(l) Member States must take all provisions of national law necessary to exclude any possibility of confusion and to prevent abuse of the CE marking.

Without prejudice to the provisions in the directive concerned relating to the application of the safeguard clause, where a Member State establishes that the CE marking has been affixed

unduly, the manufacturer, his agent or, exceptionally, where the specific directives so provide, the person responsible for placing the product in question on the Community market is obliged to make the product comply and to end the infringement under conditions imposed by the Member State. Where non-compliance continues, the Member State must take all appropriate measures to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in the safeguard clauses.

II. MODULES FOR CONFORMITY ASSESSMENT

Explanatory notes

Specific directives may allow the CE marking to be affixed to the packaging or the accompanying documentation, instead of to the product itself.

The declaration of conformity or the certificate of conformity (whichever of the two applies in the directive concerned) must cover either individual or several products and shall either accompany the product(s) covered or be kept by the manufacturer. The appropriate solution for the directive concerned will be specified.

References to Articles refer to the standard paragraphs of Annex II.B to the Council resolution of 7 May 1985 (OJ No C 136, 4. 6. 1985, p. 1), which have become standard Articles in the 'new approach' directives.

The development of computerized communication of certificates and other documents issued by notified bodies is envisaged within INSIS.

Specific directives may use modules A, C and H with additional provisions containing supplementary requirements which figure in the boxes in the modules.

Module C is designed to be used in combination with module B (EC type-examination). Modules D, E and F will also normally be used in combination with module B; however, in special cases (for example, when dealing with certain products of very simple design and construction) they may be used on their own.

Module A (internal production control)

1. This module describes the procedure whereby the manufacturer or his authorized representative established within the Community, who carries out the obligations laid down in point 2, ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. The manufacturer or his authorized manufacturer established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must establish the technical documentation described in paragraph 3 and he or his authorized representative established with the Community must keep it for a period ending at least 10 years (*) after the last product has been manufactured at the disposal of the relevant national authorities for inspection purposes.

   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.

3. Technical documentation must enable the conformity of the product with the requirements of the directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the product (**).

(*) The specific directives may alter this period.

(**) 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 referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
— results of design calculations made, examinations carried out, etc.,
— test reports.

4. The manufacturer or his authorized representative must keep a copy of the declaration of conformity with the technical documentation.

5. The manufacturer must take all measures necessary in order that the manufacturing process ensures compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the directive that apply to them.

Module Aa

This module consists of module A, plus the following supplementary requirements:

For each product manufactured one or more tests on one or more specific aspects of the product must be carried out by the manufacturer or on his behalf (*). The tests are carried out on the responsibility of a notified body chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

(*) If this option is adopted in a specific directive, the products concerned and the tests to be carried out must be specified.

or:

A notified body chosen by the manufacturer must carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, must be carried out to check the conformity of the product with the relevant requirements of the directive.

In those cases where one or more of the products checked do not conform the notified body must take appropriate measures.

The product checking must include the following aspects:

(Relevant aspects must be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

Module B (EC type-examination)

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen, representative of the production envisaged, meets the provisions of the directive that apply to it.

2. The application for the EC type-examination must be lodged by the manufacturer or his authorized representative established within the Community with a notified body of his choice.

   The application must include:

   — the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition,

   — a written declaration that the same application has not been lodged with any other notified body,

   — the technical documentation, as described in point 3.

   The applicant must place at the disposal of the notified body a specimen, repesentative of the production envisaged and hereinafter called 'type' (*). The notified body may request further specimens if needed for carrying out the test programme.

(*) A type may cover several versions of the product provided that the differences between the versions do not affect the level of safety and the other requirements concerning the performance of the product.

3. The technical documentation must enable the conformity of the product with the requirements of the directive to be assessed. It must, as far as relevant for such assessment, cover the design, manufacture and operation of the product (*).

4. The notified body must:

   4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5, as well as the components which have been designed without applying the relevant provisions of those standards;

   4.2. perform or have performed the appropriate examinations and necessary tests to check whether, where the standards referred to in Article 5 have not been applied, the solutions adopted by the manufacturer meet the essential requirements of the directive;

   4.3. perform or have performed the appropriate examinations and necessary tests to check whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied;

   4.4. agree with the applicant the location where the examinations and necessary tests will be carried out.

5. Where the type meets the provisions of the directive, the notified body must issue an EC type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, conclusions of the examination, conditions for its validity and the necessary data for identification of the approved type (**).

   A list of the relevant of the technical documentation must be annexed to the certificate and a copy kept by the notified body.

   If the manufacturer is denied a type certification, the notified body must provide detailed reasons for such denial.

   Provision must be made for an appeals procedure.

6. 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. This additional approval is given in the form of an addition to the original EC type-examination certificate.

7. Each notified body must communicate to the other notified bodies the relevant information concerning the EC type-examination certificates and additions issued and withdrawn (***).

8. The other notified bodies may receive copies of the EC type-examination certificates and/or their additions. The Annexes to the certificates must be kept at the disposal of the other notified bodies.

9. The manufacturer or his authorized representative 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.

   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.

(*) The content of the technical documentation must be laid down directive by directive in accordance with the products concerned.
For example, the documentation must contain as far as is relevant for assessment:
— a general type-description,
— 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 referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
— results of design calculations made, examinations carried out, etc.,
— test reports.

(**) The specific directives may provide for the certificate to have a period of validity.

(***) The specific directives may provide for different arrangements.

(****) The specific directives may alter this period.

Module C (conformity to type)

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative established within the Community ensures and declares that the products concerned are in conformity with the type as described in the EC type-examination certificate and satisfy the requirements of the directive that applies to them. The manufacturer or his authorized representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity.

2. The manufacturer must take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured products with the type as described in the EC type-examination certificate and with the requirements of the directive that apply to them.

3. 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.

   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.

Possible supplementary requirements:

For each product manufactured one or more tests on one or more specific aspects of the product must be carried out by the manufacturer or on his behalf (*). The tests must be carried out on the responsibility of a notified body, chosen by the manufacturer.

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

(*) If this option is adopted in a specific directive, the products concerned and the tests to be carried out must be specified.

or:

A notified body chosen by the manufacturer must carry out or have carried out product checks at random intervals. An adequate sample of the final products, taken on site by the notified body, must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, must be carried out to check the conformity of production with the relevant requirements of the directive. In those cases where one or more of the products checked do not conform, the notified body must take appropriate measures.

The product checking must include the following aspects:

(Relevant aspects must be specified here such as for example the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

On the responsibility of the notified body, the manufacturer must affix the former's identification number during the manufacturing process.

Module D (**), (production quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned [are in conformity with the type as described in the EC type-examination certificate and] satisfy the requirements of the directive that apply to them. The manufacturer or his authorized representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for EC monitoring as specified in point 4.

2. The manufacturer must operate an approved quality system for production, final product inspection and testing as specified in paragraph 3 and is subject to monitoring as specified in point 4.

(*) The specific directives may alter this period.

(**) Where this module is used without module B:
— points 2 and 3 of module A must be added between points 1 and 2 in order to incorporate the need for technical documentation,
— the words in square brackets must be deleted.

3. *Quality system*

3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body of his choice, for the products concerned.

The application 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.

3.2. The quality system must ensure compliance of the products [with the type as described in the EC type-examination certificate and] with the requirements of the directive that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of the quality programmes, plan, manuals and records.

It must contain in particular and adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

— the manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

— the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

— the means to monitor the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team must have at least one member with experience of evaluation in the product technology concerned. The evaluation procedure must include an inspection visit to the manufacturer's premises.

The decision must be notified to the manufactuer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufactuer or his authorized representative shall keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of manufacture, inspection and testing, and storage and must provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

(*) This harmonized standard will be EN 29 002, supplemented, if necessary, to take into account the specific nature of the products for which it is implemented.

4.3. The notified body must periodically (*) carry out audits to make sure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may carry out, or cause to be carried out, tests to verify that the quality system is functioning correctly, if necessary. The notified body must provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer must, for a period ending at least 10 years (**) after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6. Each notified body must give the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (***).

Module E (****) (product quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned [are in conformity with the type as described in the EC type-examination certificate and] satisfy the requirements of the directive that apply to them. The manufacturer or his authorized representative established within the Community must affix the CE mark to each product and draw up a written declaration of conformity. The CE mark must be accompanied by the identification symbol of the notified body responsible for surveillance as specified in point 4.

2. The manufacturer must operate an approved quality system for final product inspection and testing as specified in paragraph 3 and must be subject to surveillance as specified in point 4.

3. *Quality system*

3.1. The manufacturer must lodge an application for assessment of his quality system for the products concerned, with a notified body of his choice.

The application must include:

— all relevant information for the product category envisaged,

— the quality system's documentation,

— if applicable, the technical documentation of the approved type and a copy of the EC type-examination certificate.

3.2. Under the quality system, each product must be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the directive. All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must ensure a common understanding of the quality programmes, plans, manuals and records.

It must contain in particular and adequate description of:

— the quality objectives and the organizational structure, responsibilities and powers of the management with regard to product quality,

— the examinations and tests that will be carried out after manufacture,

— the means to monitor the effective operation of the quality system,

— quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

(*) In the specific directives, the frequency may be specified.
(**) The specific directives may alter this period.
(***) The specific directives may provide for different arrangements.
(****) When this module is used without module B:
— points 2 and 3 of module A must be added between points 1 and 2 in order to incorporate the need for technical documentation,
— the words in square brackets must be deleted.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It presumes conformity with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The assessment procedure must include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative must keep the notified body which has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the modified quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It must notify its decision to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

4. *Surveillance under the responsibility of the notified body*

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of inspection, testing and storage and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the technical documentation,

— the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically (**) carry out audits to ensure that the manufacturer maintains and applies the quality system and must provide an audit report to the manufacturer.

4.4. Additionally, the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been carried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years (***) after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the third indent of point 3.1,

— the updating referred to in the second paragraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final paragraph of point 3.4, points 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (****).

Module F (*****) (product verification)

1. This module describes the procedure whereby a manufacturer or his authorized representative established within the Community checks and attests that the products subject to the provisions of point 3 [are in conformity with the type as described in the EC-type examination certificate and] satisfy the requirements of the directive that apply to them.

(*) This harmonized standard will be EN 29 003, supplemented if necessary to allow for the specific features of the products for which it is implemented.

(**) The intervals between audits may be specified in the specific directives.

(***) The specific directives may alter this period.

(****) The specific directives may provide for different arrangements.

(*****) Where this module is used without module B:

— it must be supplemented by points 2 and 3 of module A (between points 1 and 2), so as to introduce the need for technical documentation,

— the next in square brackets must be deleted.

2. The manufacturer must take all measures necessary in order that the manufacturing process ensures conformity of the products [with the type as described in the EC type-examination certificate and] with the requirements of the directive that apply to them. He shall affix the CE marking to each product and shall draw up a declaration of conformity.

3. The notified body must carry out the appropriate examinations and tests in order to check the conformity of the product with the requirements of the directive either by examination and testing of every product as specified in point 4 or by examination and testing of products on a statistical basis, as specified in point 5, at the choice of the manufacturer (*).

3a. 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.

4. *Verification by examination and testing of every product*

4.1. All products must be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 or equivalent tests shall be carried out in order to verify their conformity with [the type as described in the EC-type examination certificate and] the requirements of the directive that apply to them.

4.2. The notified body must affix or cause to be affixed, its identification symbol to each approved product and draw up a written certificate of conformity relating to the tests carried out.

4.3. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

5. *Statistical verification*

5.1. The manufacturer must present his products in the form of homogeneous lots and shall take all measures necessary in order that the manufacturing process ensures the homogeneity of each lot produced.

5.2. All products must be available for verification in the form of homogeneous lots. A random sample shall be drawn from each lot. Products in a sample shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, shall be carried out to ensure their conformity with the requirements of the directive which apply to them and to determine whether the lot is accepted or rejected.

5.3. The statistical procedure must use the following elements:

(Relevant elements must be specified here such as, for example, the statistical method to be applied, the sampling plan with its operational characteristics, etc.)

5.4. In the case of accepted lots, the notified body must affix, or cause to be affixed, its identification symbol to each product and shall draw up a written certificate of conformity relating to the tests carried out. All products in the lot may be put on the market except those products from the sample which were found not to be in conformity.

If a lot is rejected, the notified body or the competent authority must take appropriate measures to prevent the putting on the market of that lot. In the event of frequent rejection of lots the notified body may suspend the statistical verification.

The manufacturer may, under the responsibility of the notified body, affix the latter's identification symbol during the manufacturing process.

5.5. The manufacturer or his authorized representative must ensure that he is able to supply the notified body's certificates of conformity on request.

Module G (unit verification)

1. This module describes the procedure whereby the manufacturer ensures and declares that the product concerned, which has been issued with the certificate referred to in point 2, conforms to the requirements of the directive that apply to it. The manufacturer or his authorized representative established within the Community must affix the CE marking to the product and draw up a declaration of conformity.

2. The notified body must examine the individual product and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5, or equivalent tests, to ensure its conformity with the relevant requirements of the directive.

(*) The manufacturer's discretion may be limited in the specific directives.
(**) The specific directives may alter this period.

The notified body must affix, or cause to be affixed, its identification number on the approved product and shall draw up a certificate of conformity concerning the tests carried out.

3. The aim of the technical documentation is to enable conformity with the requirements of the directive to be assessed and the design, manufacture and operation of the product to be understood (*).

Module H (full quality assurance)

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of paragraph 2 ensures and declares that the products concerned satisfy the requirements of the directive that apply to them. The manufacturer or his authorized representative established within the Community must affix the CE marking to each product and draw up a written declaration of conformity. The CE marking must be accompanied by the identification symbol of the notified body responsible for the surveillance as specified in point 4.

2. The manufacturer must operate an approved quality system for design, manufacture and final product inspection and testing as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. *Quality system*

   3.1. The manufacturer must lodge an application for assessment of his quality system with a notified body.

   The application must include:

   — all relevant information for the product category envisaged,

   — the quality system's documentation.

   3.2. The quality system must ensure compliance of the products with the requirements of the directive that apply to them.

   All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall ensure a common understanding of the quality policies and procedures such as quality programmes, plans, manuals and records.

   It must contain in particular an adequate description of:

   — the quality objectives and the organizational structure, responsibilities and powers of the management with regard to design and product quality,

   — the technical design specifications, including standards, that will be applied and, where the standards referred to in Article 5 will not be applied in full, the means that will be used to ensure that the essential requirements of the directive that apply to the products will be met,

   — the design control and design verification techniques, processes and systematic actions that will be used when designing the products pertaining to the product category covered,

   — the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

   — the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out,

   — the quality records, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.,

   — the means to monitor the achievement of the required design and product quality and the effective operation of the quality system.

(*) The content of the technical documentation shall be laid down directive by directive in accordance with the products concerned. As an example, the documentation shall 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 referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the directive where the standards referred to in Article 5 have not been applied,
— results of design calculations made, examinations carried out, etc.,
— test reports.

3.3. The notified body must assess the quality system to determine whether it satisfies the requirements referred to in point 3.2. It shall presume compliance with these requirements in respect of quality systems that implement the relevant harmonized standard (*).

The auditing team must have at least one member experienced as an assessor in the product technology concerned. The evaluation procedure shall include an assessment visit to the manufacturer's premises.

The decision must be notified to the manufacturer. The notification must contain the conclusions of the examination and the reasoned assessment decision.

3.4. The manufacturer must undertake to fulfil the obligations arising out of the quality system as approved and to uphold it so that it remains adequate and efficient.

The manufacturer or his authorized representative must keep the notified body that has approved the quality system informed of any intended updating of the quality system.

The notified body must evaluate the modifications proposed and decide whether the amended quality system will still satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is required.

It must notify its decision to the manufacturer. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

4. *EC surveillance under the responsibility of the notified body*

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

4.2. The manufacturer must allow the notified body entrance for inspection purposes to the locations of design, manufacture, inspection and testing, and storage, and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the quality records as foreseen by the design part of the quality system, such as results of analyses, calculations, tests, etc.,

— the quality records as foreseen by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically (**) carry out audits to make sure that the manufacturer maintains and applies the quality system and shall provide an audit report to the manufacturer.

4.4. Additionally the notified body may pay unexpected visits to the manufacturer. At the time of such visits, the notified body may carry out tests or have them carried out in order to check the proper functioning of the quality system where necessary; it must provide the manufacturer with a visit report and, if a test has been caried out, with a test report.

5. The manufacturer must, for a period ending at least 10 years (***) after the last product has been manufactured, keep at the disposal of the national authorities:

— the documentation referred to in the second indent of the second subparagraph of point 3.1,

— the updating referred to in the second subparagraph of point 3.4,

— the decisions and reports from the notified body which are referred to in the final subparagraph of point 3.4, points 4.3 and 4.4.

6. Each notified body must forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn (****).

(*) This harmonized standard shall be EN 29 001, completed if necessary to take into consideration the specificity of the products for which it is implemented.

(**) In the specific directives, the frequency may be specified.

(***) The specific directives may alter this period.

(****) The specific directives may provide for different arrangements.

Possible supplementary requirements:

Design examination

1. The manufacturer must lodge an application for examination of the design with a single notified body.

2. The application must enable the design, manufacture and operation of the product to be understood, and shall enable conformity with the requirements of the directive to be assessed.

   It must include:

   — the technical design specifications, including standards, that have been applied,

   — the necessary supporting evidence for their adequacy, in particular where the standards referred to in Article 5 have not been applied in full. This supporting evidence must include the results of tests carried out by the appropriate laboratory of the manufacturer or on his behalf.

3. The notified body must examine the application and where the design meets the provisions of the directive that apply to it must issue an EC design examination certificate to the applicant. The 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.

4. The applicant must keep the notified body that has issued the EC design examination certificate informed of any modification to the approved design. Modifications to the approved design must receive additional approval from the notified body that issued the EC design examination certificate where such changes may affect the conformity with the essential requirements of the directive or the prescribed conditions for use of the product. This additional approval is given in the form of an addition to the original EC design examination certificate.

5. The notified bodies must forward to the other notified bodies the relevant information concerning:

   — the EC design examination certificates and additions issued,

   — the EC design approvals and additional approvals withdrawn (*).

(*) The specific directives may provide for different arrangements.

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CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

	A. (Internal control of production)	B. (type examination)				G. (unit verification)	H. (full quality assurance)
DESIGN	Manufacturer Keeps technical documentation at the disposal of national authorities Aa Intervention of notified body	Manufacturer submits to notified body — Technical documentation — Type Notified body — Ascertains conformity with essential requirements — Carries out tests, if necessary — Issues EC type-examination certificate				Manufacturer — Submits technical documentation	EN 29001 Manufacturer — Operates an approved quality system (QS) for design Notified body — Carries out surveillance of the QS — Verifies conformity of the design (1) — Issues EC design examination certificate (1)
		C. (conformity to type)	D. (production quality assurance)	E. (product quality assurance)	F. (product verification)		
PRODUCTION	A. Manufacturer — Declares conformity with essential requirements — Affixes the CE marking Aa Notified body — Tests on specific aspects of the product (1) — Product checks at random intervals (1)	Manufacturer — Declares conformity with approved type — Affixes the CE marking Notified body — Tests on specific aspects of the product (1) — Product checks at random intervals (1)	EN 29002 Manufacturer — Operates an approved quality system (QS) for production and testing — Declares conformity with approved type — Affixes the CE marking Notified body — Approves the QS — Carries out surveillance of the QS	EN 29003 Manufacturer — Operates an approved quality system (QS) for inspection and testing — Declares conformity with approved type, or to essential requirements — Affixes the CE marking Notified body — Approves the QS — Carries out surveillance of the QS	Manufacturer — Declares conformity with approved type, or with essential requirements — Affixes the CE marking Notified body — Verifies conformity — Issues certificate at conformity	Manufacturer — Submits product — Declares conformity — Affixes the CE marking Notified body — Verifies conformity with essential requirements — Issues certificate of conformity	Manufacturer — Operates an approved QS for production and testing — Declares conformity — Affixes the CE marking Notified body — Carries out surveillance of the QS

(1) Supplementary requirements which may be used in specific Directives.

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