ANNEX I

REFERENCE PROVISIONS FOR COMMUNITY HARMONISATION LEGISLATION FOR PRODUCTS

Chapter R1

Definitions

Article R1

Definitions

For the purposes of this ... [act] the following definitions shall apply:

1. ‘making available on the market’ shall mean any supply of a product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge;

2. ‘placing on the market’ shall mean the first making available of a product on the Community market;

3. ‘manufacturer’ shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;

4. ‘authorised representative’ shall mean any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

5. ‘importer’ shall mean any natural or legal person established within the Community who places a product from a third country on the Community market;

6. ‘distributor’ shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

7. ‘economic operators’ shall mean the manufacturer, the authorised representative, the importer and the distributor;

8. ‘technical specification’ shall mean a document that prescribes technical requirements to be fulfilled by a product, process or service;

9. ‘harmonised standard’ shall mean a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive;

10. ‘accreditation’ shall have the meaning assigned to it by Regulation (EC) No 765/2008;

11. ‘national accreditation body’ shall have the meaning assigned to it by Regulation (EC) No 765/2008;

12. ‘conformity assessment’ shall mean the process demonstrating whether specified requirements relating to a product, process, service, system, person or body have been fulfilled;

13. ‘conformity assessment body’ shall mean a body that performs conformity assessment activities including calibration, testing, certification and inspection;

14. ‘recall’ shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;

15. ‘withdrawal’ shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

16. ‘CE marking’ shall mean a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;

17. ‘Community harmonisation legislation’ shall mean any Community legislation harmonising the conditions for the marketing of products.

Chapter R2

Obligations of economic operators

Article R2

Obligations of manufacturers

1 When placing their products on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in … [reference to the relevant part of the legislation].

2 Manufacturers shall draw up the required technical documentation and carry out the conformity assessment procedure applicable or have it carried out.

3 Manufacturers shall keep the technical documentation and the EC declaration of conformity for ... [period to be specified in proportion to the lifecycle of the product and the level of risk] after the product has been placed on the market.

4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in product design or characteristics and changes in the harmonised standards or in technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

5 Manufacturers shall ensure that their products bear a type, batch or serial number or other element allowing their identification, or, where the size or nature of the product does not allow it, that the required information is provided on the packaging or in a document accompanying the product.

6 Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product. The address must indicate a single point at which the manufacturer can be contacted.

7 Manufacturers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

8 Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the applicable Community harmonisation legislation shall immediately take the necessary corrective measures to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9 Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of the product, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article R3

Authorised representatives

1 A manufacturer may, by a written mandate, appoint an authorised representative.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

Article R4

Obligations of importers

1 Importers shall place only compliant products on the Community market.

2 Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the required conformity marking or markings and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article [R2(5) and (6)].

3 Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the product or, where that is not possible, on its packaging or in a document accompanying the product.

4 Importers shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in … [reference to the relevant part of the legislation].

6 When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed products, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of such monitoring.

7 Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity with the Community harmonisation legislation applicable shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

8 Importers shall, for ... [period to be specified in proportion to the lifecycle of the product and the level of risk], keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9 Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Article R5

Obligations of distributors

1 When making a product available on the market distributors shall act with due care in relation to the requirements applicable.

2 Before making a product available on the market distributors shall verify that the product bears the required conformity marking or markings, that it is accompanied by the required documents and by instructions and safety information in a language which can be easily understood by consumers and other end-users in the Member State in which the product is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article [R2(5) and (6)] and Article [R4(3)].

3 Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in ... [reference to the relevant part of the legislation].

4 Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with the Community harmonisation legislation applicable shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the product available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5 Distributors shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.

Article R6

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this ... [act] and he shall be subject to the obligations of the manufacturer under Article [R2], where he places a product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

Article R7

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities, for ... [period to be specified in proportion to the lifecycle of the product and the level of risk]:

(a) any economic operator who has supplied them with a product;

(b) any economic operator to whom they have supplied a product.

Chapter R3

Conformity of the product

Article R8

Presumption of conformity

Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the requirements covered by those standards or parts thereof, set out in … [reference to the relevant part of the legislation].

Article R9

Formal objection to a harmonised standard

1 When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in … [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.

2 In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3 The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article R10

EC declaration of conformity

1 The EC declaration of conformity shall state that the fulfilment of requirements specified in … [reference to relevant part of the legislation] has been demonstrated.

2 The EC declaration of conformity shall have the model structure set out in Annex III of Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, shall contain the elements specified in the relevant modules set out in Annex II of that Decision and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the product is placed or made available.

3 By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product.

Article R11

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article R12

Rules and conditions for affixing the CE marking

1 The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents, where the legislation concerned provides for such documents.

2 The CE marking shall be affixed before the product is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

3 The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase.

4 Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and take appropriate action in the event of improper use of the marking. Member States shall also provide for penalties for infringements, which may include criminal sanctions for serious infringements. Those penalties shall be proportionate to the seriousness of the offence and constitute an effective deterrent against improper use.

Chapter R4

Notification of conformity assessment bodies

Article R13

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this ... [act].

Article R14

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of Article [R20].

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article [R15(1) to (6)]. In addition it shall have arrangements to cover liabilities arising out of its activities.

4 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article R15

Requirements relating to notifying authorities

1 A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2 A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3 A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4 A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5 A notifying authority shall safeguard the confidentiality of the information it obtains.

6 A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article R16

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article R17

Requirements relating to notified bodies

1 For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 A conformity assessment body shall be established under national law and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses.

4 A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by … [reference to relevant part of the legislation] and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

7 The personnel responsible for carrying out conformity assessment activities shall have the following:

8 The impartiality of the conformity assessment bodies, their top level management and of the assessment personnel shall be guaranteed.

9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under … [reference to the

relevant part of the legislation] or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant Community harmonisation legislation and apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article R18

Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* it shall be presumed to comply with the requirements set out in Article [R17] in so far as the applicable harmonised standards cover those requirements.

Article R19

Formal objection to a harmonised standard

Where a Member State or the Commission has a formal objection to the harmonised standards referred to in Article [R18], the provisions of Article [R9] shall apply.

Article R20

Subsidiaries of and subcontracting by notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article [R17] and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under … [reference to the relevant part of the legislation].

Article R21

Accredited in-house bodies

1 An accredited in-house body may be used to carry out conformity assessment activities for the undertaking of which it forms a part for the purpose of implementing the procedures set

out in [Annex II — modules A1, A2, C1 or C2]. That body shall constitute a separate and distinct part of the undertaking and shall not participate in the design, production, supply, installation, use or maintenance of the products it assesses.

2 An accredited in-house body shall meet the following requirements:

3 An accredited in-house body shall not be notified to the Member States or the Commission, but information concerning its accreditation shall be given by the undertaking of which it forms a part or by the national accreditation body to the notifying authority at the request of that authority.

Article R22

Application for notification

1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 That application shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article [R17] of this ... [act].

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article [R17].

Article R23

Notification procedure

1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article [R17].

2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and product or products concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate as referred to in Article [R22(2)], the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article [R17].

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

6 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article R24

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to a notified body.

2 The Commission shall make publicly available the list of the bodies notified under this ... [act], including the identification numbers that have been allocated to them and the activities for which they have been notified.

Article R25

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article [R17], or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article R26

Challenge of the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article R27

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in … [the relevant part of the legislation].

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

3 Where a notified body finds that requirements laid down in … [the relevant part of the legislation] or corresponding harmonised standards or technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a conformity certificate.

4 Where, in the course of the monitoring of conformity following the issue of a certificate, a notified body finds that a product no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate if necessary.

5 Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates, as appropriate.

Article R28

Information obligation on notified bodies

1 Notified bodies shall inform the notifying authority of the following:

2 Notified bodies shall provide the other bodies notified under this ... [act] carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article R29

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article R30

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under … [the relevant act or other Community legislation] are put in place and properly operated in the form of a … [sectoral or cross sectoral] group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that or those group or groups, directly or by means of designated representatives.

Chapter R5

Safeguard procedures

Article R31

Procedure for dealing with products presenting a risk at national level

1 Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a product covered by this ... [act] presents a risk to the health or safety of persons or to other aspects of public interest protection covered by this ... [act], they shall carry out an evaluation in relation to the product concerned covering all the requirements laid down in this ... [act]. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

2 Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the Community.

4 Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the product's being made available on their national market, to withdraw the product from that market or to recall it.

5 The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either:

6 Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the product concerned, and, in the event of disagreement with the notified national measure, of their objections.

7 Where, within …. [period to be specified] of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8 Member States shall ensure that appropriate restrictive measures are taken in respect of the product concerned, such as withdrawal of the product from their market, without delay.

Article R32

Community safeguard procedure

1 Where, on completion of the procedure set out in Article [R31(3) and (4)], objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Community legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

2 If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant product is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.

3 Where the national measure is considered justified and the non-compliance of the product is attributed to shortcomings in the harmonised standards referred to in [Article R31(5)(b)], the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.

Article R33

Compliant products which present a risk to health and safety

1 Where, having performed an evaluation under Article [R31(1)], a Member State finds that although a product is in compliance with this ... [act], it presents a risk to the health or safety of persons or to other aspects of public interest protection, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2 The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the Community.

3 The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

4 The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not, and where necessary, propose appropriate measures.

5 The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article R34

Formal non-compliance

1 Without prejudice to Article [R31], where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

2 Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the market.

ANNEX II

CONFORMITY ASSESSMENT PROCEDURES

Module AInternal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain 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., and
— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Conformity marking and declaration of conformity

4.1. 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.

4.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module A1 Internal production control plus supervised product testing

1. Internal production control plus supervised product testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. 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., and
— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Product checks

For each individual product manufactured, one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests are carried out either by an accredited in-house body or under the responsibility of a notified body chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. Conformity marking and declaration of conformity

5.1. 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.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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

1. Internal production control plus supervised product checks at random intervals is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 4, and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. 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., and

— test reports.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

4. Product checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks of the product, taking into account, *inter alia*, the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standard and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product performs within acceptable limits, with a view to ensuring conformity of the product.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

5. Conformity marking and declaration of conformity

5.1. 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.

5.2. The manufacturer shall draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in point 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module B EC-type examination

1. EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it.

2. EC-type examination may be carried out in either of the following manners:

— examination of a specimen, representative of the production envisaged, of the complete product (production type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer shall lodge an application for EC-type examination with a single notified body of his choice.

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

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

— the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. 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., and

  — test reports,

— the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,

— the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, 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.

4. The notified body shall:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the notified body shall issue an EC-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EC-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

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. Such modifications shall require additional approval in the form of an addition to the original EC-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EC-type 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.

Each notified body shall inform the other notified bodies concerning the EC-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EC-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EC-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

Module C Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Conformity marking and declaration of conformity

3.1. 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 described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

3.2. 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 10 years after the

product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module C1 Conformity to type based on internal production control plus supervised product testing

1. Conformity to type based on internal production control plus supervised product testing is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EC-type examination certificate and with the requirements of the specific legislative instrument that apply to them.

3. Product checks

For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the corresponding requirements of the legislative instrument. At the choice of the manufacturer, the tests shall be carried out either by an accredited in-house body or under the responsibility of a notified body, chosen by the manufacturer.

Where the tests are carried out by a notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. Conformity marking and declaration of conformity

4.1. 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 described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

4.2. 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 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

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

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EC-type examination certificate and with the requirements of the specific legislative instrument that apply to them.

3. Product checks

At the choice of the manufacturer, either an accredited in-house body or a notified body, chosen by the manufacturer, shall carry out product checks or have them carried out at random intervals determined by the body, in order to verify the quality of the internal checks on the product, taking into account, *inter alia*, the technological complexity of the products and the quantity of production. An adequate sample of the final products, taken on site by the notified body before the placing on the market, shall be examined and appropriate tests as identified by the relevant parts of the harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to check the conformity of the product with the relevant requirements of the legislative instrument. Where a sample does not conform to the acceptable quality level, the body shall take appropriate measures.

The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the product performs within acceptable limits, with a view to ensuring conformity of the product.

Where the tests are carried out by notified body, the manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. Conformity marking and declaration of conformity

4.1. 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 described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

4.2. 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 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module D Conformity to type based on quality assurance of the production process

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. Quality system

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

The application shall include:
— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
— a written declaration that the same application has not been lodged with any other notified body,
— all relevant information for the product category envisaged,
— the documentation concerning the quality system,
— the technical documentation of the approved type and a copy of the EC-type examination certificate.

3.2. The quality system shall ensure that the products are in conformity with the type described in the EC-type examination certificate and comply with the requirements of the legislative instrument that apply to them.

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 shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:
— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
— 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 on the personnel concerned, etc., and

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those 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.

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. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall 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 shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall 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 on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The

notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of 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.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module D1 Quality assurance of the production process

1. Quality assurance of the production process is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain 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., and
— test reports.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in point 5, and shall be subject to surveillance as specified in point 6.

5. Quality system

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

The application shall include:
— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
— a written declaration that the same application has not been lodged with any other notified body,
— all relevant information for the product category envisaged,
— the documentation concerning the quality system,
— the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument 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 shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:
— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
— 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 on the personnel concerned, etc.,
— the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those 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.

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. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether reassessment is necessary.

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

6. Surveillance under the responsibility of the notified body

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

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
— the quality system documentation,
— the technical documentation referred to in point 2,
— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them

carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. Conformity marking and declaration of conformity

7.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

8. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 5.1,

— the change referred to in point 5.5, as approved,

— the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authorities of 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.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module E Conformity to type based on product quality assurance

1. Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 4.

3. Quality system

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

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

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

— all relevant information for the product category envisaged,

— the documentation concerning the quality system, and

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

3.2. The quality system shall ensure compliance of the products with the type described in the EC-type examination certificate and with the applicable requirements of the legislative instrument.

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 shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

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

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

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

— the means of monitoring the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those 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.

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. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, fifth indent, in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall 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 shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall 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 on the personnel concerned, etc.

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of 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.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module E1 Quality assurance of final product inspection and testing

1. Quality assurance of final product inspection and testing is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 4 and 7, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain 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., and
— test reports.

3. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

4. Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned as specified in point 5 and shall be subject to surveillance as specified in point 6.

5. Quality system

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

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
— a written declaration that the same application has not been lodged with any other notified body,
— all relevant information for the product category envisaged,
— the documentation concerning the quality system, and
— the technical documentation referred to in point 2.

5.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument 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 shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:
— the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,
— the examinations and tests that will be carried out after manufacture,
— the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.,
— the means of monitoring the effective operation of the quality system.

5.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 5.2.

It shall presume conformity with those 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.

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. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 2 in order to verify the manufacturer's ability to identify the relevant requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

5.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

5.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 5.2 or whether a reassessment is necessary.

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

6. Surveillance under the responsibility of the notified body

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

6.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:

— the quality system documentation,

— the technical documentation referred to in point 2,

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

6.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

6.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

7. Conformity marking and declaration of conformity

7.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 5.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

8. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation referred to in point 5.1,

— the change referred to in point 5.5, as approved,

— the decisions and reports of the notified body referred to in points 5.5, 6.3 and 6.4.

9. Each notified body shall inform its notifying authorities of 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.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

10. Authorised representative

The manufacturer's obligations set out in points 3, 5.1, 5.5, 7 and 8 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module F Conformity to type based on product verification

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5.1 and 6, and ensures and declares on his sole responsibility that the products concerned, which have been subject to the provisions of point 3, are in conformity with the type described in the EC-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EC-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EC-type examination certificate and with the appropriate requirements of the legislative instrument.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out, at the choice of the manufacturer either by examination and testing of every product as specified in point 4 or by examination and testing of the products on a statistical basis as specified in point 5.

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

4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical specifications, or equivalent tests, shall be carried out in order to verify conformity with the approved type described in the EC-type examination certificate and with the appropriate requirements of the legislative instrument. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the product has been placed on the market.

5. Statistical verification of conformity

5.1. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

5.2. A random sample shall be taken from each lot according to the requirements of the legislative instrument. All products in a sample shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or technical

specifications, or equivalent tests, shall be carried out in order to ensure their conformity with the applicable requirements of the legislative instrument and to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

5.3. If a lot is accepted, all products of the lot shall be considered approved, except for those products from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect to the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

5.4. If a lot is rejected, the notified body or the competent authority shall take appropriate measures to prevent that lot's being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

6. Conformity marking and declaration of conformity

6.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product that is in conformity with the approved type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities, for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products.

7. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 2 and 5.1.

Module F1 Conformity based on product verification

1. Conformity based on product verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 6.1 and 7 and ensures and declares on his sole responsibility that the products concerned, which

have been subject to the provisions of point 4, are in conformity with the requirements of the legislative instrument that apply to them.

2. Technical documentation

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain 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., and

— test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the applicable requirements of the legislative instrument.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests to check the conformity of the products with the applicable requirements of the legislative instrument.

The examinations and tests to check the conformity with those requirements shall be carried out, at the choice of the manufacturer, either by examination and testing of every product as specified in point 5, or by examination and testing of the products on a statistical basis as specified in point 6.

5. Verification of conformity by examination and testing of every product

5.1. All products shall be individually examined and appropriate tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, shall be carried out to verify conformity with the requirements that apply to them. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

5.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

6. Statistical verification of conformity

6.1. The manufacturer shall take all measures necessary so that the manufacturing process ensures the homogeneity of each lot produced, and shall present his products for verification in the form of homogeneous lots.

6.2. A random sample shall be taken from each lot according to the requirements of the legislative instrument. All products in the sample shall be individually examined and appropriate tests set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to establish conformity with the requirements that apply to them, shall be carried out to determine whether the lot is accepted or rejected. In the absence of such a harmonised standard and/or technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

6.3. If a lot is accepted, all products of the lot shall be considered approved, except for those products from the sample that have been found not to satisfy the tests.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

If a lot is rejected, the notified body shall take appropriate measures to prevent that lot being placed on the market. In the event of the frequent rejection of lots the notified body may suspend the statistical verification and take appropriate measures.

7. Conformity marking and declaration of conformity

7.1. The manufacturer shall affix the conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

7.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

If the notified body referred to in point 5 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products.

8. If the notified body agrees and under its responsibility, the manufacturer may affix the notified body's identification number to the products during the manufacturing process.

9. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in points 3 and 6.1.

Module G Conformity based on unit verification

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 5, and ensures and declares on his sole responsibility that the product concerned, which has been subject to the provisions of point 4, is in conformity with the requirements of the legislative instrument that apply to it.

2. Technical documentation

The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall, wherever applicable, contain 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., and
— test reports.

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the legislative instrument.

4. Verification

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or technical specifications, or equivalent tests, to check the conformity of the product with the applicable requirements of the legislative instrument, or have them carried out. In the absence of such a harmonised standard and/or

technical specification the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument and, under the responsibility of the notified body referred to in point 4, the latter's identification number to each product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. Authorised representative

The manufacturer's obligations set out in points 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module H Conformity based on full quality assurance

1. Conformity based on full quality assurance is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 5, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

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

3. Quality system

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

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— the technical documentation for one model of each category of products intended to be manufactured. The technical documentation shall, wherever applicable, contain 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,

— the documentation concerning the quality system, and
— a written declaration that the same application has not been lodged with any other notified body.

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument 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. That quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational 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 relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument 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 on the personnel concerned, etc.,
— the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those 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.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1, second indent, to verify the manufacturer's ability to identify the applicable requirements of the legislative instrument and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall 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 shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality system documentation,

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

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

4.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

5. Conformity marking and declaration of conformity

5.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

5.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the technical documentation referred to in point 3.1,

— the documentation concerning the quality system referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authorities of 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.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

Module H1 Conformity based on full quality assurance plus design examination

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 6, and ensures and declares on his sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the products concerned as specified in point 3 and shall be subject to surveillance as specified in point 5. The adequacy of the technical design of the products shall have been examined in accordance with point 4.

3. Quality system

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

The application shall include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,

— all relevant information for the product category envisaged,

— the documentation concerning the quality system,

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

3.2. The quality system shall ensure compliance of the products with the requirements of the legislative instrument 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. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

— the quality objectives and the organisational 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 relevant harmonised standards and/or technical specifications will not be applied in full, the means that will be used to ensure that the essential requirements of the legislative instrument 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 on the personnel concerned, etc.,

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

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those 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.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant product field and product technology concerned, and knowledge of the applicable requirements of the legislative instrument. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision.

The notification shall contain the conclusions of the audit and the reasoned assessment decision.

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

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

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

3.6. Each notified body shall inform its notifying authorities of 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.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

4. Design examination

4.1. The manufacturer shall lodge an application for examination of the design with the notified body referred to in point 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the product, and to assess the conformity with the requirements of the legislative instrument that apply to it. It shall include:

— the name and address of the manufacturer,

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

— the technical documentation. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design and operation of the product. The technical documentation shall, wherever applicable, contain 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., and
  - test reports,

— the supporting evidence for the adequacy of the technical design. This supporting evidence shall mention any documents that have been used, 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.

4.3. The notified body shall examine the application, and where the design meets the requirements of the legislative instrument that apply to the product it shall issue an EC design examination certificate to the manufacturer. The certificate shall give the name

and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined design to be evaluated, and to allow for in-service control, where applicable.

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.

4.4. The notified body shall keep itself apprised of any changes in 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 shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

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. Such modifications shall require additional approval — from the notified body that issued the EC design examination certificate — in the form of an addition to the original EC design examination certificate.

4.5. Each notified body shall inform its notifying authorities 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.

Each notified body shall inform the other notified bodies of the EC design examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, of the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EC design examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and of the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EC design examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of the certificate.

4.6. The manufacturer shall keep a copy of the EC design examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

5. Surveillance under the responsibility of the notified body

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

5.2. The manufacturer shall, for assessment purposes, allow the notified body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

— the quality system documentation,

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

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

5.3. The notified body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

5.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits, the notified body may, if necessary, carry out product tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

6. Conformity marking and declaration of conformity

6.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument, and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product that satisfies the applicable requirements of the legislative instrument.

6.2. The manufacturer shall draw up a written declaration of conformity for each product model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity shall identify the product model for which it has been drawn up and shall mention the number of the design examination certificate.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

7. The manufacturer shall, for a period ending at least 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

— the documentation concerning the quality system referred to in point 3.1,

— the change referred to in point 3.5, as approved,

— the decisions and reports of the notified body referred to in points 3.5, 5.3 and 5.4.

8. Authorised representative

The manufacturer's authorised representative may lodge the application referred to in points 4.1 and 4.2 and fulfil the obligations set out in points 3.1, 3.5, 4.4, 4.6, 6 and 7, on his behalf and under his responsibility, provided that they are specified in the mandate.

TABLE: CONFORMITY ASSESSMENT PROCEDURES IN COMMUNITY LEGISLATION

DESIGN								
	A. Internal production control		B. Type examination		G. Unit verification		H. Full quality assurance	

a	Supplementary requirements which may be used in sectoral legislation.
b	Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
c	Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.
d	Except for requirements relating to customer satisfaction and continual improvement.

												EN ISO 9001:2000[d]	
	Manufacturer — keeps technical documentation at the disposal of national authorities		Manufacturer submits to notified body technical documentation supporting evidence for the adequacy of the technical design solution specimen(s), representative of the production envisaged, as required							Manufacturer — submits technical documentation		Manufacturer operates an approved quality system for design — submits technical documentation	
			Notified body — ascertains conformity with essential requirements — examines technical documentation and supporting evidence to assess adequacy of the technical design — for specimen(s): carries out tests, if necessary — issues EC-type examination certificate									Notified body — carries out surveillance of the QS	
												H1	
												Notified body — verifies conformity of design[a] — issues EC-design examination certificate[a]	
PRODUCTION		C.	Conformity to type		Product quality assurance		Product quality assurance			Product verification			
				EN ISO 9001:2000[b]		EN ISO 9001:2000[c]							
	A.	**C.**											

a Supplementary requirements which may be used in sectoral legislation.

b Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.

c Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.

d Except for requirements relating to customer satisfaction and continual improvement.

Manufacturer			Manufacturer			Manufacturer			Manufacturer			Manufacturer			Manufacturer			Manufacturer		
—			declares conformity with essential requirements			operates an approved quality system for production, final inspection and testing			operates an approved quality system for final inspection and testing			declares conformity with approved type			submits product			declares conformity		operates an approved QS for production, final inspection and testing
—			affixes required conformity marking			declares conformity with approved type			declares conformity with approved type			affixes required conformity marking			affixes required conformity marking			—		declares conformity
						affixes required conformity marking			affixes required conformity marking									—		affixes required conformity marking
A1.			**C1.**			**D1.**			**E1.**			**F1.**								
Accredited in-house body			Accredited in-house body			declares conformity to essential requirements			declares conformity to essential requirements			declares conformity to essential requirements								
or notified body			or notified body			—			affixes required conformity marking			affixes required conformity marking			affixes required conformity marking					
—	tests		—	tests																
	on specific aspects of the product[a]			on specific aspects of the product[a]																
						Notified body			Notified body			Notified body			Notified body			Notified body		
A2.			**C2.**			—			approves			approves			verifies			verifies		carries out surveillance of
—	Product		Product	checks		at			the QS			the QS			conformity to			conformity to		

a	Supplementary requirements which may be used in sectoral legislation.
b	Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
c	Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.
d	Except for requirements relating to customer satisfaction and continual improvement.

		random intervals[a]	random intervals[a]	carries out surveillance of the QS	carries out surveillance of the QS	essential requirements issues certificate of conformity	essential requirements issues certificate of conformity	the QS		

a	Supplementary requirements which may be used in sectoral legislation.
b	Except for subclause 7.3 and requirements relating to customer satisfaction and continual improvement.
c	Except for subclauses 7.1, 7.2.3, 7.3, 7.4, 7.5.1, 7.5.2, 7.5.3 and requirements relating to customer satisfaction and continual improvement.
d	Except for requirements relating to customer satisfaction and continual improvement.

ANNEX III

EC DECLARATION OF CONFORMITY

1. No … (unique identification of the product):
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
4. Object of the declaration (identification of product allowing traceability. It may include a photograph, where appropriate):
5. The object of the declaration described above is in conformity with the relevant Community harmonisation legislation: …
6. References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) … performed … (description of intervention) … and issued the certificate: …
8. Additional information:

Signed for and on behalf of: ……

(place and date of issue):

(name, function) (signature):

Status:
Point in time view as at 31/01/2020.

Changes to legislation:
There are currently no known outstanding effects for the Decision No 768/2008/EC of the European Parliament and of the Council.