Pursuant to Article 24, paragraph 9 of the Law on Product Safety ("Official Gazette of the Republic of Macedonia" No. 33/06, 63/07, 24/11 and 51/11), the Government of the Republic of Macedonia on its session held on _____ adopted the following

Decree
for common framework for placing products on the market and the manner of notification for acquisition of the capacity of bodies for conformity assessment and the manner of notification of bodies for conformity assessment in the European Commission

General principles

Article 1

This Decree regulates the common framework for the marketing of products, obligations for economic operators , conformity assessment procedure and the procedure of notification for acquiring capacity of the conformity assessment bodies and the procedure of designation (notification) of the conformity assessment bodies within the European Commission according the applicable legislation

Article 2

(1) When placing products on the Republic of Macedonia and European Union market, economic operators shall, in relation to their respective roles in the supply chain, be responsible for the compliance of their products with all applicable legislation.

(2) Economic operators shall be responsible for ensuring that all information they provide with regard to their products is accurate, complete and in compliance with rules applicable in Republic of Macedonia and European Union.

Level of protection of public interests

Article 3

1. As regards the protection of public interests, before to placing the safe products on on the Republic of Macedonia and European Union market, the Republic of Macedonia and European Union harmonisation legislation shall restrict itself to setting out the essential requirements determining the level of such protection and shall express those requirements in terms of the results to be achieved.

Where recourse to essential requirements is not possible or not appropriate, in view of the objective of ensuring the adequate protection of consumers, public health and the environment or other aspects of public interest protection, detailed specifications may be set out in the Republic of Macedonia and European Union harmonisation legislation concerned.

2. In case where the Republic of Macedonia and European Union harmonisation legislation sets out essential requirements, it shall provide for recourse to be had to harmonised standards, adopted in accordance with Low of standardization and low of safety of product , which shall express those requirements in technical terms and which shall, alone or in conjunction with other harmonised standards, provide for the presumption of conformity with those requirements, while maintaining the possibility of setting the level of protection by other means.

Conformity assessment procedures

Article 4

1. Where harmonisation legislation requires conformity assessment to be performed in respect of a particular product, the procedures which are to be used shall be chosen from among the modules set out and specified in Annex I, in accordance with the following criteria:

(a) whether the module concerned is appropriate to the type of product;

(b) the nature of the risks entailed by the product and the extent to which conformity assessment corresponds to the type and degree of risk;

(c) where third party involvement is mandatory, the need for the manufacturer to have a choice between quality assurance and product certification modules set out in Annex I;

(d) the need to avoid imposing modules which would be too burdensome in relation to the risks covered by the legislation concerned.

2. Where a product is subject to several technical legislation in Republic of Macedonia and European Union Community and is within the scope of this Decree, consistency among conformity assessment procedures shall be ensured by the legislator.

3. The modules referred to in paragraph 1 shall be applied as appropriate to the product concerned and in accordance with the instructions set out in those modules.

4. For custom-made products and small series production, the technical and administrative conditions relating to conformity assessment procedures shall be alleviated.

5. When applying the modules referred to in paragraph 1, and wherever applicable and relevant, in the technical regulations can require additional requirements :

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

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

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

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

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

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

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

(h) if the notified body- body for conformity assessment carries out periodic audits, specify their frequency.

6. When applying the modules referred to in paragraph 1, and if appropriate apply the technical regulations shall have:

(a) where product checks and/or verification are performed, determine the products concerned, the appropriate tests, the adequate sampling schemes, the operational characteristics of the statistical method to be applied and the corresponding action to be taken by the notified body and/or the manufacturer;

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

7. An appeal procedure against decisions of the notified body shall be available.

EC declaration of conformity

Article 5

(1) If the harmonized technical regulations require a statement from the manufacturer that meeting the requirements regarding the product is proven (EC declaration of conformity), it brings all the individual declaration of harmonized technical regulations applicable to the product.

(2) EC declaration of conformity is given in Aannex II.

Conformity assessment

Article 6

(1) Where harmonization legislation requires conformity assessment, it may provide for that assessment to be carried out by public authorities, manufacturers or notified bodies.

(2) Where Community harmonisation legislation provides for conformity assessment to be carried out by public authorities, the legislation shall provide that the conformity assessment bodies on which those authorities rely for technical assessments must comply with the same criteria as those set out in this Decree for notified bodies.

Definitions

Article 7

(1) Certain terms used in this Decree shall have the following meanings :

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 market in Republic of Macedonia and European Union ;

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 in Republic of Macedonia and European Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

5)" importer "means any natural or legal person established in the Republic of Macedonia, who places a product from a third country on the on Macedonia market ;

6) "distributor" shell mean any natural or legal person established in the Republic of Macedonia included in the supply chain and whose activities do not affect product safety;

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 and they are taken and harmonized in the national standards from the side of Institute of Standardization of the Republic of Macedonia ;

10) "accreditation" means certification by the national body for accreditation body that a conformity assessment meets the requirements laid down in harmonized national standards and where applicable, any additional requirements, including those provided in the relevant sectoral accreditation schemes necessary to perform a specific activity of conformity assessment;

11) "national accreditation body" is the Institute for Accreditation of Macedonia, authorized by the Government of the Republic of Macedonia;

12) "Designated or notified body for conformity assessment" is the authorized body reported to the European Commission and Member States to carry out activities for conformity assessment vkluchuvakji calibration, testing, certification and verification;

13) "authorized body reporting" is a body responsible for monitoring of notified bodies and enforcement procedure for notifying the European Commission and Member States;

14) “conformity assessment procedure” shall mean any procedure that directly or indirectly confirms that the essential requirements to be met by the products are fulfilled;

15) "recall" shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;

16)"withdrawal" shall mean any measure aimed at preventing a product in the supply chain from being made available on the market;

17) "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

18) " harmonisation legislation" means legislation in Macedonia, which harmonized requirements for the marketing of products

Obligations of economic operators

Article 8

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 technical regulations.

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

Where compliance of a product with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity and affix the conformity marking.

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for period of 10 years 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.

When deemed appropriate with regard to the risks presented by a product, manufacturers 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 any such monitoring.

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 Republic of Macedonia.

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 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 market surveillance authority in Republic of Macedonia and the competent national authorities in 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 Macedonian language and Cyrillic alphabeta . 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.

Authorised representatives

Article 9

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

The obligations laid down in Article 8 paragraph (1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

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:

(a) keep the EC declaration of conformity and the technical documentation at the disposal of **market surveillance authority** for period should be appointed in proportion to the life cycle of the product and the level of risk.

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product;

(c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by products covered by their mandate.

Obligations of importers

Article 10

1. Importers placed on the Macedonian market only safe products that comply with technical regulations.

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 8 paragraph (5) and (6) of this Decree.

Where an importer considers or has reason to believe that a product is not in conformity with technical regulations and specification , he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

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 Low for safety of product and technical regulations.

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 has grown in circulation is not in conformity with the Law on product safety and technical regulations immediately take the necessary corrective measures to bring that product in conformity to remove or withdraw, if appropriate. Moreover, if the product carries a risk, importers shall immediately inform the authorities for market surveillance, giving details, in particular, non-compliance and remedial measures taken.

8. Importers should keep a copy of the EC declaration of conformity and technical documentation in accordance with the period indicated on the product in relation to the life of the product and the level of risk. They should be available to the authorities for market surveillance at their 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 Macedonian language and Cyrillic alphabeta. 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.

Obligations of distributors

Article 11

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 8 paragraph (5) and (6) and Article 10 paragraph (3) of this Decree.

Where a distributor considers or has reason to believe that a product is not in conformity with the Law on product safety and technical regulations, he shall not make the product available on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

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 the Law on product safety and technical regulations.

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 Law on product safety and technical regulations, 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 authorities for market surveillance , giving details, in particular, of the non-compliance and of any corrective measures taken.

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

Cases in which obligations of manufacturers apply to importers and distributors

Article 12

An importer or distributor shall be considered a manufacturer for the purposes of this Decree and he shall be subject to the obligations of the manufacturer under Article (8) from this Decree , 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.

Identification of economic operators

Article 13

Economic operators, the authorities for market surveillance should inform for:

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

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

The requirement of paragraph 1 of this article is for the period specified under the shelf life of the product and the level of risk.

III. Product Conformity

Presumption of conformity

Article 14

Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Gazette of the Republic Makedinaja is considered to be in conformity with the requirements covered by those standards or parts thereof, specified in the technical regulations and technical specifications

Formal objection to a harmonised standard

Article 15

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 in the technical regulations and technical specifications, 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.

EC declaration of conformity

Article 16

1.EC declaration of conformity certifies that the requirements specified in technical regulations and are determined.

2.The contents of the EC declaration of conformity is given иn Annex II of this Decree.

3. With the preparation of the EC declaration of conformity, the manufacturer assumes responsibility for product conformity.

General principles of the CE marking

Article 17

CE marking is regulated in Chapter IV of the Law on Market Surveillance ("Official Gazette of the Republic of Macedonia" No..48/10).

Rules and conditions for affixing the CE marking

Article 18

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.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4. With the national law established mechanisms that ensure proper application of the CE and determined measures are taken in case of improper use of the mark. distraction from improper use.

II. PROCEDURE AND CONDITIONS FOR INFORMATION OF BODIES OF CONFORMITY ASSESSMENT

Notification

Article 19

Republic of Macedonia shell notify the European Commission and other Member states of bodies authorised to carry out tasks related to conformity assessment under this Decree.

Notifying authorities

Article 20

(1) Authority a notification to the authorized bodies for conformity assessment in the European Commission and Member States is the Ministry of Economy.

(2) Ministry of economy 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 and any resulting changes in reportable bodies.

Requirements relating to notifying authorities

Article 21

(1) A notifying authority shall safeguard the confidentiality of the information it obtains.
(2) A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Requirements relating to notified bodies

Article 22

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

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.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be 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.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

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 according the technical regulations and low and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.***

At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

(a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

(b) descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

(c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities**.**

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

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

(b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of Community harmonisation legislation and of its implementing regulations;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

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

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

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 any provision of national law is effective enforcement, with the exception of the competent authorities of the Member States and the Republic of Macedonia who are performing such activities. Property rights are protected by law.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardization activities undertaken by the Institute for Standardization of the Republic of Macedonia and the European Union and coordinating the activities of the group of notified bodies for conformity assessment established under the relevant legislation of the Republic of Macedonia and apply as general guidance the administrative decisions and documents that have occurred as a result of work of that group.

Presumption of conformity

Article 23

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 Republic of Macedonia it shall be presumed to comply with the requirements set out in Article 22 in so far as the applicable harmonised standards cover those requirements.

Formal objection to a harmonised standard

Article 24

If the Republic of Macedonia or the Commission have a formal objection to the harmonized standards referred to in Article 23, the provisions of Article 15 shell apply.

Subsidiaries of and subcontracting by notified bodies

Article 25

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 22 from this Decree and shall inform the notifying authority – Ministry of economy .

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 for conformity assessment shall keep at the disposal to the Ministry of economy the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under the lie and technical regulations.

Accredited in-house bodies

Article 26

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 I — 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:

(a) it shall be accredited in accordance with Law for accreditation;

(b) the body and its personnel shall be organisationally identifiable and have reporting methods within the undertaking of which they form a part which ensure their impartiality and demonstrate it to the relevant national accreditation body;

(c) neither the body nor its personnel shall be responsible for the design, manufacture, supply, installation, operation or maintenance of the products they assess nor shall they engage in any activity that might conflict with their independence of judgment or integrity in relation to their assessment activities;

(d) the body shall supply its services exclusively to the undertaking of which it forms a part.

3. Information regarding the accreditation of the accredited body composition provides enterprise of which this body is an integral part or the national body for accreditation by the authorized body for the notification, which shall inform the Commission and Member States

Procedure for reporting bodies for conformity assessment

Application for notification

Article 27

1. A conformity assessment body shall submit an application for notification to the Ministry of economy.

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 issued by the Institute for Accreditation of Republic of Macedonia attesting that the conformity assessment body fulfils the requirements laid down in Article 22 of this Decree.

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 22 of this Decree.

Notification procedure

Article 28

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in technical regulations.

2. Ministry of Economy shell notify the European Commission and Member States using electronic notification tool developed and maneged by the European 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 27 paragraph 2 from this Decree , Ministry of Economy shall provide to 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 22 from this Decree.

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.

Only such a body shall be considered a notified body for the purposes of this Decree.

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

Identification numbers and lists of notified bodies

Article 29

1. The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several technical regulations .

2. Ministry of economy shall make publicly available the list of the bodies notified under this Decree, including the identification numbers that have been allocated to them and the activities for which they have been notified.

3. Ministry of economy shall ensure that list is kept up to date.

Changes to notifications

Article 30

1) If the Ministry of Economy established or is notified that notified body for conformity assessment ceased to meet the requirements specified in technical regulations and its decision on authorization is revoked, shall withdraw the notification.

2) The withdrawal of the notification referred to in paragraph 1 of this Article, the Ministry of Economy informed the European Commission and Member States in accordance with the procedure laid down in Article 28 paragraph 2 of this Decree.

3) In the case of paragraph 1 of this Article, the Ministry of Economy will take appropriate measures to provide other notified body for conformity assessment to continue to process cases of the body whose reporting is withdrawn.

Challenge of the competence of notified bodies

Article 31

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. Ministry of economy 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.Ministry of economy shall ensure that all sensitive information obtained by the European commission 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 Ministry of economy accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Operational obligations of notified bodies

Article 32

1) Notified bodies shall carry out conformity assessment in accordance with the procedures for assessing conformity to technical regulations provided.

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) If the notified body finds that requirements laid down in the harmonized technical regulations or relevant harmonized standards or technical specifications are not met by the manufacturer requires a manufacturer to take appropriate corrective measures and will not issue a certificate of conformity.

4) In the course of the monitoring of compliance issued on the certificate, notified body finds that the product no longer fit, require the manufacturer to take appropriate remedial measures to reverse 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.

Information obligation on notified bodies

Article 33

1. Notified bodies shall inform the Ministry of economy of the following:

(a) any refusal, restriction, suspension or withdrawal of a certificate;

(b) any circumstances affecting the scope of and conditions for notification;

(c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

(d) on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Decree 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.

Exchange of experience

Article 34

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

Coordination of notified bodies

Article 35

(1) Ministry of Economy provides adequate coordination and cooperation between notified bodies established and properly managed in the form of sectoral or inter-group or groups of notified bodies.
(2) Ministry of Economy undertakes activities that all notified bodies participate in that or those groups directly or through appointed representatives.

Safeguard procedures

Procedure for dealing with products presenting a risk at national level

Article 36

1. Where the market surveillance authorities of the Republic of Macedonia have taken action according the low , or where they have sufficient reason to believe that a product covered by this technical regulations presents a risk to the health or safety of persons or to other aspects of public interest protection covered by technical regulations, they shall carry out an evaluation in relation to the product concerned covering all the requirements laid down in this Decree. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.

Where, in the course of that evaluation, the market surveillance authorities find that the product does not comply with the requirements laid down in this technical regulations , they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a 10 days, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

2. If measures taken under Article 13 of Law on market surveillance and oversight bodies in the market believe that non-compliance is not restricted to their national territory shall inform the Commission and other Member States of the results of conformity assessment and the measures they demanded to be taken by economic operators.

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 in R. Macedonia and the E. Union.

4. Where the relevant economic operator does not take adequate corrective action within the period of 10 days referred to in paragraph 1, line 2, and the authorities for market surveillance shall take all necessary provisional measures to withdraw the product or go to can become available in Republic of Macedonia. For all these measures taken immediately notify the European Commission and other Member States of such measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary to identify non -copliant product, the origin of product , the nature of the non-compliance alleged and the risk involved, the nature and duration of measures taken by the market surveillance authorities of R. Macedonia 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:

(a) failure of the product to meet requirements relating to the health or safety of persons or to other aspects of public interest protection laid down in this Decree; or

(b) shortcomings in the harmonised standards referred to in technical regulations conferring a presumption of conformity.

6. Republic of Macedonia nitiating 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 the period 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 Republic of Macedonia , that measure shall be deemed justified.

8. Republic of Macedonia 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.

Community safeguard procedure

Article 37

1.Where, on completion of the procedure set out in Article 36 paragraph 3 and 4 from this Decree, objections are raised against a measure taken by side of Republic of Macedonia , 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 measures taken by the authorities for market surveillance of the Republic of Macedonia. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

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

2.If the measure taken by the authorities for market surveillance of the Republic of Macedonia 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 same measure is considered unjustified, market surveilens body from R.M shell withdrow 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 paragraph 5 point 6 from Article 16 from this Decree , 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.

Compliant products which present a risk to health and safety

Article 38

1. Where, having performed an evaluation under Article 36 from this Decree,market surveillance body finds that although a product is in compliance with this Decree , 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 in Republic of Macedonia and throughout the Community.

3.Ministry of economy 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, nature of risk and the nature and duration of measures taken by the authorities for market surveillance.

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.

Formal non-compliance

Article 39

1. Without prejudice to Article 36, where market surveillance authorities require from the relevant economic operator to put an end to the non –compliance if one came to the following conclusions:

(a) the conformity marking has been affixed in violation of Article 19 or of Article 20 from this Decree;

(b) the conformity marking has not been affixed;

(c) the EC declaration of conformity has not been drawn up;

(d) the EC declaration of conformity has not been drawn up correctly;

(e) technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 from this article persists, market surveillance authorities 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.

III. TRANSITIONAL AND FINAL PROVISIONS

Article 40

The provisions of Articles of this Decree shall apply from the date of accession of the Republic of Macedonia into the European Union, except for products that are subject of the European protocol/agreement on conformity assessment (ACCA), which establishes the free movement of goods between Republic of Macedonia and the European Union, on the day of entry into force of that protocol/agreement.

Article 41

The date of commencement of application of this Decree, shall be repealed Decree on the manner of appointment (notification) of bodies for conformity assessment in the European Commission ("Official Gazette of the Republic of Macedonia" no. 105/07).

Article 42

This Decree shall enter into force on the eight days after its publication in the Official Gazette of the Republic of Macedonia.

ANNEX I

Module A

Internal 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

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.

ANNEX II

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):
