STATUTORY INSTRUMENTS

S.I. No. ?????????? of 2016

EUROPEAN UNION (EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES) REGULATIONS, 2016.

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EUROPEAN UNION (EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES) REGULATIONS 2016.

Arrangement of Regulations

PART 1 – PRELIMINARY AND GENERAL

PART 2 - OBLIGATIONS OF ECONOMIC OPERATORS

PART 3 - CONFORMITY OF PRODUCTS

S.I. No. ????????????? of 2016

EUROPEAN UNION (EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES) REGULATIONS, 2016

I, Gerard Nash, Minister of State at the Department of Jobs, Enterprise and Innovation, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014, hereby make the following regulations:

PART 1

PRELIMINARY AND GENERAL

Citation and Commencement.

1. (1) These Regulations may be cited as the European Union (Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres) Regulations, 2016.

(2) These Regulations shall come into operation on the 20th April 2016.

Interpretation

2. (1) In these Regulations, except where the context otherwise requires—

"accreditation" means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

"Act of 2005" means the Safety, Health and Welfare at Work Act 2005 (Number 10 of 2005);

"Annex" means an Annex to Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 unless it is indicated that reference to some other Annex otherwise specified is intended;

"Article" means an Article to Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 unless it is indicated that reference to some other Article otherwise specified is intended;

"authorised representative" means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

“the Authority” means the Health and Safety Authority;

“CE marking” means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

“components” means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;

“conformity assessment” means the process demonstrating whether the essential health and safety requirements of Directive 2014/34/EU have been fulfilled;

“conformity assessment body” means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

“the Directive” means Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014;

“distributor” means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;

“economic operators” means the manufacturer, the authorised representative, the importer and the distributor;

“equipment” means machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition;

“equipment category” means the classification of equipment, within each equipment-group, specified in Schedule 1 of these Regulations, determining the requisite level of protection to be ensured;

“equipment-group I” means equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust, comprising equipment categories M 1 and M 2 as set out in Schedule 1 of these Regulations;

“equipment-group II” means equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 as set out in Schedule 1 of these Regulations;

“essential health and safety requirements” means the requirements specified in Schedule 2 of these Regulations;

“EU declaration of conformity” means a declaration set out in the form specified in Schedule 10 of these Regulations;

“explosive atmosphere” means a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture;

“harmonised standard” means harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

“importer” means any natural or legal person established within the Union who places a product from a third country on the Union market;

“inspector” means a person authorised in accordance with Regulation 19(3);

“intended use” means the use of a product prescribed by the manufacturer by assigning the equipment to a particular equipment-group and category or by providing all the information which is required for the safe functioning of a protective system, device or component;

“Irish National Accreditation Board” means the national body with responsibility for the accreditation of laboratories, certification bodies and inspection bodies, and notified to the European Commission as being the sole accreditation body for Ireland in line with Regulation (EC) No 765/2008;

“making available on the market” means any supply of a product for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

“manufacturer” means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trade mark or uses it for his own purposes;

“Member State” means a Member of the European Union and a reference to a Member State includes a reference to a State in the European Economic Area;

“the Minister” means the Minister for Jobs, Enterprise and Innovation;

“notified body” means a conformity assessment body appointed in accordance with Regulation 16;

“placing on the market” means the first making available of a product on the Union market;

“potentially explosive atmosphere” means an atmosphere which could become explosive due to local and operational conditions;

“protective systems” means devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems;

“recall” means any measure aimed at achieving the return of a product that has already been made available to the end- user;

“the Regulations of 1999” means the European Communities (Equipment & Protective Systems Intended for use in Potentially Explosive Atmospheres) Regulations (S.I. No. 83 of 1999);

“technical specification” means a document that prescribes technical requirements to be fulfilled by a product;

“Union harmonisation legislation” means any Union legislation harmonising the conditions for the marketing of products;

“withdrawal” means any measure aimed at preventing a product in the supply chain from being made available on the market.

(2) A word or expression that is used in these Regulations and is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

(3) In these Regulations—

(a) a reference to a Regulation or a Schedule is a reference to a Regulation of or a Schedule to these Regulations unless it is indicated that reference to some other Regulations is intended,

(b) a reference to a paragraph or a subparagraph is a reference to the paragraph or the subparagraph of the provision in which the reference occurs unless it is indicated that reference to some other provision is intended,

(c) a reference to an Annex is a reference to an Annex to the Directive unless it is indicated that reference to some other Annex is intended, and

(d) a reference to an Article is a reference to an Article to the Directive unless it is indicated that reference to some other Article is intended.

Application

3. (1) Subject to Regulation 4 these Regulations shall apply to the following, hereinafter referred to as “products” -

(a) equipment and protective systems intended for use in potentially explosive atmospheres;

(b) safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres but required for, or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion;

(c) components intended to be incorporated into equipment and protective systems referred to in subparagraph (a).

(2) These Regulations shall apply to distance selling.

(3) These Regulations shall not apply to—

(a) medical devices intended for use in a medical environment;

(b) equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances;

(c) equipment intended for use in domestic and non-commercial environments where potentially explosive atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas;

(d) personal protective equipment covered by Council Directive (89/686/EEC) of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment;

(e) seagoing vessels and mobile offshore units together with equipment on board such vessels or units;

(f) means of transport, i.e. vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded from the scope of these Regulations and the Directive;

(g) the equipment covered by point (b) of Article 346(1) of the Treaty on the Functioning of the European Union.

Exception for Trade Fairs, Exhibitions, Demonstrations.

4. A person may not show equipment and protective systems, intended for use in potentially explosive atmospheres, that are not in conformity with these Regulations and the Directive at trade fairs, exhibitions and demonstrations, unless—

(a) a clearly visible sign is displayed indicating—

(i) that the products concerned do not comply with the Directive, and

(ii) that the products concerned are not available for sale until they are brought into conformity with the Directive,

and

(b) appropriate safety measures are observed at the trade fair, exhibition or demonstration concerned.

PART 2

OBLIGATIONS OF ECONOMIC OPERATORS

Obligation of Manufacturers

5. (1) Before placing a product on the market or using it for their own purposes, a manufacturer shall ensure that -

(a) the product has been designed and manufactured in accordance with the essential health and safety requirements set out in Schedule 2,

(b) technical documentation referred to in Schedules 3 to 9 of these Regulations has been drawn up,

(c) relevant conformity assessment procedures referred to in Regulation 12 have been carried out,

(d) where compliance of a product, other than a component, with the applicable requirements has been demonstrated by that procedure, an EU declaration of conformity is drawn up in the format set out in Schedule 10 and CE marking is affixed to the product in accordance with Regulation 14,

(e) where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure, a written attestation of conformity is drawn up as referred to in Regulation 12(3),

(f) each product is accompanied by a copy of the EU declaration of conformity or of the attestation of conformity, as appropriate. Where a large number of products are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy.

(2) A manufacturer shall keep the technical documentation and the EU declaration of conformity or, where applicable, the attestation of conformity for 10 years after the product has been placed on the market.

(3) A manufacturer shall ensure that products in series production remain in conformity with these Regulations and the Directive. Changes in a product design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a product is declared shall be adequately taken into account.

(4) When deemed appropriate, by the Authority or a market surveillance authority in another Member State, with regard to the risks presented by a product, a manufacturer shall, to protect the health and safety of end-users, carry out sample testing of products made available on the market, 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) A manufacturer shall ensure that products which it has placed on the market 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) A manufacturer shall ensure that products, other than components, which it has placed on the market bear the specific marking of explosion protection and, where applicable, the other markings and information referred to in paragraph 1.0.5 of Schedule 2.

(7) A manufacturer shall indicate, on the product, its name, registered trade name or registered trade mark and the postal address at which it can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and the competent national authority where the product is to be put on the market.

(8) A manufacturer shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users and the competent national authority where the product is to be put on the market. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

(9) A manufacturer who considers or has reason to believe that a product which it has placed on the market is not in conformity with these Regulations and the Directive shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it as appropriate. Furthermore, where the product presents a risk, the manufacturer shall immediately inform the Authority and the competent national authorities in other Member States in which it made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(10) A manufacturer shall, further to a reasoned request from the Authority or from a competent national authority in another Member State, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product with these Regulations and the Directive, in a language which can be easily understood by that authority. The manufacturer shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by *products* which it has placed on the market.

(11) A manufacturer shall ensure that any corrective action required by a market surveillance authority is taken in respect of all the products concerned which that manufacturer has made available on the market throughout the Union.

Authorised Representatives

6. (1) A manufacturer may, by a written mandate, appoint an authorised representative. The obligations laid down in Regulation 5(1) and the obligation to draw up technical documentation referred to in Regulation 5(2) 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 EU declaration of conformity or, where applicable, the attestation of conformity and the technical documentation at the disposal of the Authority and national market surveillance authorities in other Member States for 10 years after the product has been placed on the market;

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

(c) co-operate with the Authority or competent national authorities in other Member States, at their request, on any action taken to eliminate the risks posed by products covered by the authorised representative's mandate.

Obligations of Importers

7. (1) An importer shall not place a product on the market unless the product is compliant with these Regulations.

(2) Before placing a product on the market an importer shall ensure that -

(a) the appropriate conformity assessment procedures referred to in Regulation 12 have been carried out by the manufacturer,

(b) the manufacturer has drawn up the technical documentation,

(c) the product bears the CE marking,

(d) where applicable, the product is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents, and

(e) the manufacturer has complied with the requirements set out in Regulations 5(5), 5(6) and 5(7).

(3) Where an importer considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Schedule 2, it 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, the Authority and the market surveillance authorities in any other Member State where that importer has placed the product on the market.

(4) An importer shall indicate on the product its name, registered trade name or registered trade mark and the postal address at which it can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The contact details shall be in a language which can be easily understood by the end-users, the Authority and the competent national authority where the product is to be put on the market.

(5) An importer shall ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by the end-users, the Authority and the competent national authority where the product is to be put on the market.

(6) An importer shall ensure that, while a product is under their responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Schedule 2.

(7) When deemed appropriate, by the Authority or a market surveillance authority in another Member State, with regard to the risks presented by a product, an importer shall, to protect the health and safety of end-users, carry out sample testing of products made available on the market, 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.

(8) An importer who considers or has reason to believe that a product which it has placed on the market is not in conformity with these Regulations shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall as appropriate. Furthermore, where the product presents a risk, the importer shall immediately inform the Authority and the competent national authorities in other Member States where it has made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(9) An importer shall, for 10 years after the product has been placed on the market, keep a copy of the EU declaration of conformity or, where applicable, of the attestation of conformity at the disposal of the Authority and ensure that the technical documentation can be made available to the Authority, upon request.

(10) An importer shall, further to a reasoned request from the Authority or a competent national authority in another Member State, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product in a language which can be easily understood by that authority. It shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which it has placed on the market.

(11) An importer shall ensure that any corrective action, required by the Authority or by a market surveillance authority in another Member State, is taken in respect of all the products concerned which that importer has made available on the market throughout the Union.

Obligations of Distributors

8. (1) A distributor shall act with due care in relation to the requirements of these Regulations when making a product available on the market.

(2) Before making a product available on the market a distributor shall ensure that -

(a) the product bears the CE marking,

(b) where applicable, that it is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents and

(c) it is accompanied by instructions and safety information, in a language which can be easily understood by the end-users, the Authority and the competent national authority where the product is to be put on the market and

(d) the manufacturer and the importer have complied with the requirements set out in Regulation 5(5), 5(6) and 5 (7) and Regulation 7(4) respectively.

(3) Where a distributor considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Schedule 2, it 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 Authority and the market surveillance authority in any other Member State where the distributor has placed the product on the market.

(4) A distributor shall ensure that, while a product is under its responsibility, its storage or transport conditions do not jeopardise compliance of the product with the essential health and safety requirements set out in Schedule 2.

(5) A distributor, who considers or has reason to believe that a product which it has made available on the market is not in conformity with these Regulations, shall ensure 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, a distributor shall immediately inform the Authority and the competent national authorities of the Member States in which it has made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(6) A distributor shall, further to a reasoned request from the Authority or a competent national authority in another Member State, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product. It shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by products which it has made available on the market.

(7) A distributor shall ensure that any corrective action required by a market surveillance authority is taken in respect of all the products concerned which that distributor has made available on the market throughout the Union.

Cases in which Obligations of Manufacturers apply to Importers and Distributors

9. An importer or distributor shall be considered a manufacturer for the purposes of these Regulations and shall be subject to the obligations of the manufacturer under Regulation 5, where he places a product on the market under his name or trade mark or modifies a product already placed on the market in such a way that compliance with these Regulations may be affected.

Identification of Economic Operators

10 (1) Economic operators shall, on request, identify the following to the Authority or to a market surveillance authority in a Member State:

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

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

(2) Economic operators shall be able to present the information referred to in paragraph (1) for 10 years after they have been supplied with the product and for 10 years after they have supplied the product.

PART 3

CONFORMITY OF PRODUCTS

Products Manufactured in Conformity with a Harmonised Standard

11. A product manufactured in conformity with a harmonised standard, the references to which have been published in the Official Journal of the European Union, shall be presumed to comply with the essential health and safety requirements covered by such a harmonised standard unless there are reasonable indications that the said product does not comply.

Conformity Assessment Procedures

12. (1) The procedures to be followed for assessing the conformity of products shall be as follows:

(a) for equipment-groups I and II, equipment-categories M 1 and 1, the EU-type examination set out in Schedule 3, in conjunction with either of the following:

— conformity to type based on quality assurance of the production process set out in Schedule 4,

— conformity to type based on product verification set out in Schedule 5;

(b) for equipment-groups I and II, equipment categories M 2 and 2;

(i) in the case of internal combustion engines and electrical equipment in these groups and categories, the EU-type examination set out in Schedule 3, in conjunction with either of the following:

— conformity to type based on internal production control plus supervised product testing set out in Schedule 6,

— conformity to type based on product quality assurance set out in Schedule 7;

(ii) in the case of other equipment in these groups and categories, internal production control set out in Schedule 8 and the communication of the technical documentation provided for in Schedule 8, paragraph 2, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

(c) for equipment-group II, equipment category 3, internal production control set out in Schedule 8;

(d) for equipment-groups I and II, in addition to the procedures referred to in subparagraphs (a), (b) and (c) of this paragraph, conformity based on unit verification set out in Schedule 9 may also be followed.

(2) The procedure referred to in subparagraph (a) or (d) of paragraph (1) shall be used for conformity assessment of protective systems.

(3) The procedures referred to in paragraph (1) shall be applied in respect of components with the exception of the affixing of the CE marking and the drawing up of the EU declaration of conformity. A written attestation of conformity shall be issued by the manufacturer, declaring the conformity of the components with the applicable provisions of the Directive and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential health and safety requirements set out in Schedule 2 applicable to finished equipment or protective systems.

(4) With regard to the safety aspects referred to in paragraph 1.2.7 of Schedule 2, in addition to the conformity assessment procedures referred to in paragraphs (1) and (2), the procedure referred to in Schedule 8 may also be followed.

(5) By derogation from paragraphs (1), (2) and (4), the Authority may on a duly justified request in writing, authorise the placing on the market and putting into service products other than components in respect of which the procedures referred to in paragraphs (1), (2) and (4) have not been applied and the use of which is in the interests of protection. This authorisation is only applicable to products placed on the market or put into service in the Republic of Ireland.

(6) Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs (1) to (4) shall be drawn up in a language that can be easily understood by end-users and the market surveillance authority in the Member State in which it is to be made available to end-users.

EU Declaration of Conformity

13. (1) The EU declaration of conformity shall state that the fulfilment of the essential health and safety requirements set out in Schedule 2 has been demonstrated.

(2) The EU declaration of conformity shall have the model structure set out in Schedule 10, shall contain the elements specified in the relevant conformity assessment procedures set out in Schedules 3 to 9 and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the product is placed or made available on the market.

(3) Where a product is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

(4) By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in these Regulations and the Directive.

Rules and Conditions for Affixing CE Marking and other Markings

14. (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.

(2) The CE marking shall be affixed before the product is placed on the market.

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

(4) The identification number of the notified body shall be affixed—

(a) by the notified body itself, or

(b) under the instructions of the notified body, by the manufacturer.

(5) The CE marking and, where applicable, the identification number of the notified body shall be followed by the specific marking of explosion protection  , the symbols of the equipment-group and category and, where applicable, the other markings and information referred to in paragraph 1.0.5 of Schedule 2. Products that are designed for a particular explosive atmosphere shall be marked accordingly.

(6) The CE marking and the markings, symbols and information referred to in paragraph (5) and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use.

(7) A person shall not affix a CE marking, in a manner that is in contravention of these Regulations, to a product which conforms with these Regulations.

(8) A person shall not affix a CE marking to a product to which these Regulations apply but which does not conform with these Regulations.

PART 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Designation of Minister as the Notifying Authority

15. (1) The Minister is designated as the notifying authority in the State for the purposes of Articles 17, 18, 19, 20, 23, 24, 25, 27, 28(2) and 31 of the Directive.

(2) The Minister where necessary shall appoint an appeal panel for the purposes of Regulations 16(7) and 17(6).

Notification of Notified Bodies

16. (1) A conformity assessment body shall meet the requirements of Articles 21 and 23 of the Directive for the purposes of notification.

(2) Application for notification by a conformity assessment body shall be in accordance with Article 24 of the Directive.

(3) The Minister may where—

(a) a conformity assessment body has made an application in accordance with Article 24 of the Directive, and

(b) he or she is satisfied that the conformity assessment body meets the requirements set out in Article 21 of the Directive,

grant notification to the conformity assessment body.

(4) The Irish National Accreditation Board shall carry out the following activities on behalf of the Minister—

(a) the setting up and carrying out the necessary procedures for the assessment and accreditation of conformity assessment bodies, and

(b) the monitoring of notified bodies, including compliance with Article 23 of the Directive.

(5) Where the Minister has ascertained or has been informed that a notified body appointed by the Minister no longer meets the requirements laid down in Article 21 or Article 23 of the Directive or that it is failing to fulfil its obligations, the Minister shall restrict, suspend or withdraw

notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(6) The Minister shall inform the notified body concerned of its decision and allow the body an opportunity to make representations to it.

(7) Where a notified body is aggrieved by a decision of the Minister to restrict, suspend or withdraw its notification, the notified body may appeal the decision to an appeal panel of such number of independent and suitably qualified persons as the Minister decides. The decision of the appeal panel is final other than on a point of law which lies to the High Court.

Operational Obligations of Notified Bodies

17. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedules 3 to 7 and Schedule 9 of these Regulations. They shall also participate in the sectoral group of notified bodies established in accordance with Article 33 of the Directive.

(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. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the requirements of these Regulations.

(3) Where a notified body finds that the essential health and safety requirements set out in Schedule 2 or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity.

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

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

(6) A manufacturer may, within 21 days of the date of withdrawal, restriction or suspension of a certificate held by the manufacturer, appeal the decision of the notified body to an appeal panel established by the Minister.

(7) An appeal panel shall comprise such number of independent and suitably qualified persons as the Minister decides. The decision of an appeal panel is final other than on a point of law which lies to the High Court.

(8) A notified body shall inform the Minister of the matters referred to in Regulation 18 of these Regulations.

Information Obligation on Notified Bodies

18. (1) Notified bodies shall inform the Minister of the following:

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

(b) any circumstances affecting the scope of or 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 other bodies notified under the Directive 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.

PART 5

MARKET SURVEILLANCE AND INSPECTIONS

Market Surveillance Authority

19. (1) The Health and Safety Authority shall be the market surveillance authority for products within the scope of these Regulations.

(2) The Authority shall perform its market surveillance duties in accordance with Articles 35, 36, 37 and 38 of the Directive.

(3) A person who for the time being stands appointed as an inspector under section 62 of the Act of 2005 shall be an inspector for the purpose of these Regulations and the Directive.

(4) An inspector shall, when exercising any power conferred on him or her by these Regulations, if requested to do so by any person affected, produce the certificate of authorisation or a copy of it furnished to him or her under section 62(2) of the Act of 2005 together with a form of personal identification.

Inspections and Surveillance

20. While carrying out surveillance of products made available on the market the Authority shall take due account of the presumption of the conformity of products bearing a CE marking unless there are reasonable indications that the said product does not comply.

Powers of Inspectors

21. (1) An inspector shall, for the purposes of these Regulations, have power to do any one or more of the following:

(a) subject to paragraph (4), at any time enter, inspect, examine and search any place;

(b) inquire into, search, examine and inspect—

(i) any place referred to in subparagraph (a),

(ii) any activity, installation, process, procedure, matter or thing at or

in that place, and

(iii) any product or any record relating to such product, to ascertain whether these Regulations have been or are being complied with and, for that purpose, take with him or her and use any equipment or materials he or she consider necessary;

(c) require that that place and anything at or in it be left undisturbed for so long as is reasonably necessary for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(d) require the person in charge to produce to the inspector—

(i) any product or partly completed product which is in the possession or under the control of such person, and

(ii) any records, and in the case of such information in a non-legible form, to reproduce it in a legible form, and to give to the inspector such information as the inspector may reasonably require in relation to any entries in those records;

(e) inspect and take copies of or extracts from any such records or any electronic information system at that place, including in the case of information in a non-legible form, copies of or extracts from such information in a permanent legible form or require that such copies be provided;

(f) require a person at or in that place by whom or on whose behalf a computer is or has been used to produce or store records or any person having control of, or otherwise concerned with the operation of the computer, to afford the inspector access thereto and all reasonable assistance as the inspector may require;

(g) remove from that place and retain the records (including documents stored in a non-legible form) and copies taken and detain the records for such period as the inspector reasonably considers to be necessary for further examination or until the conclusion of any legal proceedings;

(h) require that records at or in that place be maintained for such period as may be reasonable;

(i) require the person in charge to give the inspector such information as the inspector may reasonably require for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(j) require the person in charge to give the inspector such assistance and facilities within the person's power or control as are reasonably necessary to enable the inspector to exercise any of his or her powers under these Regulations;

(k) require by notice, at a time and place specified in the notice, any person (including the person in charge) to give the inspector any information that the inspector may reasonably require in relation to the place, any product, equipment, item, activity, installation or procedure at or in the place, and to produce to the inspector any records that are under that person's power or control;

(l) examine any person whom the inspector reasonably believes to be able to give to the inspector information relevant to any search, examination, investigation, inspection or inquiry under these Regulations and require the person to answer such questions as the inspector may ask relative to the search, examination, investigation, inspection or inquiry and to sign a declaration of the truth of the answers;

(m) require that any procedure be followed for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(n) take any measurements or photographs or make any tape, electrical or other recordings that the inspector considers necessary for the purposes of any search, examination, investigation, inspection or inquiry under these Regulations;

(o) take samples of air, soil, water or waste at or near that place;

(p) where appropriate, install, use and maintain at that place monitoring instruments, systems and seals for the purposes of these Regulations;

(q) at that place, or at any other location, carry out, or have carried out, such testing, examination or analysis of any item or product found at that place, as he or she reasonably considers to be necessary, and for that purpose—

(i) require the person in charge to supply to the inspector without charge any product, equipment or item, or samples thereof, or

(ii) remove, or have removed, to another location, any product, equipment or item, or samples thereof;

(r) cause any product found at that place in respect of which there has been or there appears to the inspector to have been a contravention of these Regulations, to be subjected to any testing, examination or analysis in accordance with subparagraph (q) (but not so as to damage or destroy it unless necessary for the purposes of these Regulations) and where an inspector proposes to exercise the power conferred by this subparagraph in the case of any such product found at any place, he or she shall, if so requested by the person in charge, cause anything that is to be done by virtue of that power to be done in the presence of that person;

(s) remove and retain for such period as is necessary any product, equipment or item found at that place for all or any of the following purposes:

(i) to examine or arrange for the examination, testing or analysis of the product, equipment or item;

(ii) to ensure that it is not tampered with before the examination of it under subparagraph (i) is completed;

(iii) to ensure that it is available for use as evidence in any proceedings;

(t) where necessary—

(i) require the disposal or destruction of any product in respect of which there has been or there appears to the inspector to have been a contravention of these Regulations at the expense of the person in charge, or remove that product and arrange for it to be disposed or destroyed of at the expense of the person in charge, and

(ii) require that such disposal or destruction shall be—

(I) such as will prevent the product from being used or placed on the market, and

(II) in compliance with requirements under the Waste Management Acts 1996 to 2003;

(u) require the removal from the market of a product by the person who has placed that product on the market, where it appears to the inspector that, in relation to that, these Regulations have been contravened.

(2) Where a product is found at a place, and an inquiry is made by an inspector in the course of a search, examination, investigation or inspection as to the identity of the person who supplied that product, the person in charge shall give the inspector the name and address of the supplier from whom the product was purchased or otherwise obtained.

(3) Before exercising any of the powers conferred by subparagraphs (q) to (t) of paragraph (1), an inspector shall, in so far as it is practicable, consult such persons as appear to him or her to be appropriate for the purpose of ascertaining what dangers, if any, there may be in doing what he or she proposes to do under those subparagraphs.

(4) An inspector shall not enter a dwelling other than—

(a) with the consent of the occupier, or

(b) in accordance with a warrant of the District Court issued under paragraph (7) authorising such entry.

(5) The Authority may authorise such and so many other persons as it considers appropriate to accompany an inspector in the performance of his or her functions.

(6) Where an inspector in the exercise of his or her powers under this Regulation is prevented from entering any place, an application may be made to the District Court for a warrant under paragraph (7) authorising such entry.

(7) Without prejudice to the powers conferred on an inspector by or under any other provision of this Regulation, if a judge of the District Court is satisfied by information on oath of an inspector that there are reasonable grounds for believing that—

(a) there is any product, equipment or item at any place or any records (including documents stored in a non-legible form) or information, relating to a place or to a product, that the inspector requires to inspect for the purposes of these Regulations, held at any place, or

(b) there is, or such an inspection is likely to disclose, evidence of a contravention of these Regulations,

the judge may issue a warrant authorising an inspector, accompanied by such other inspectors or such other competent persons as may be appropriate or members of the Garda Síochána as may be necessary, at any time or times, within one month from the date of issue of the warrant, on production of the warrant if requested, to enter the place, if necessary by the use of reasonable force, and perform the functions conferred on an inspector by or under these Regulations.

(8) Where an inspector has reasonable grounds for apprehending any serious obstruction in the performance of his or her functions or otherwise considers it necessary, he or she may be accompanied by a member or members of the Garda Síochána and by any other person or persons authorised by the Authority, when performing any functions conferred on him or her by or under these Regulations.

(9) Where an inspector, upon reasonable grounds, believes that a person has committed an offence under these Regulations he or she may require that person to provide him or her with the person's name and the address at which the person ordinarily resides.

(10) A statement or admission made by a person pursuant to a requirement under subparagraph (i), (k) or (l) of paragraph (1) shall not be admissible in proceedings brought against that person for an offence (other than an offence under Regulation 29 (4) relating to a breach of, or failure to comply with, an obligation in the said subparagraph (i), (k) or (l))

Measures Entailing Refusal or Restriction

22. An Inspector who is of the opinion that a person has not complied with the administrative requirements –

(a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Regulation 14 of these Regulations;

(b) the CE marking, where required, has not been affixed;

(c) the specific marking of explosion protection  , the symbols of the equipment-group and category and, where applicable, the other markings and information have been affixed in violation of point 1.0.5 of Schedule 2 or have not been affixed;

(d) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of Regulation 14 or has not been affixed;

(e) the EU declaration of conformity or the attestation of conformity, as appropriate, does not accompany the product;

(f) the EU declaration of conformity or, where required, the attestation of conformity has not been drawn up correctly;

(g) technical documentation is either not available or not complete;

(h) the information referred to in Regulation 5(7) or 7(4) is absent, false or incomplete;

(i) any other administrative requirement provided for in Regulation 5 or 7 is not fulfilled.

may issue a direction in writing to put an end to the non-compliance observed within a specified timeframe.

Contravention Notice

23. (1) An inspector who is of the opinion that a person—

(a) is contravening or has contravened any of the provisions of these Regulations, or

(b) has failed to comply with a direction under Regulation 22,

may serve a notice (in these Regulations referred to as a “contravention notice”) on the person who has or may reasonably be presumed to have control of the activity concerned.

(2) A contravention notice shall—

(a) state that the inspector is of the opinion referred to in paragraph (1),

(b) specify the grounds for the inspector being of the opinion referred to in paragraph (1) and specify the Regulation or Regulations concerned,

(c) identify the relevant provision in respect of which that opinion is held,

(d) direct the person, where required, to—

(i) remedy the contravention or the matters occasioning that notice,

(ii) remove a product from the market,

(iii) recall the product,

(iv) dispose the product,

(v) destroy the product,

by a date specified in the notice that shall not be earlier than the end of the period within which an appeal may be made under paragraph (6),

(e) include information regarding the making of an appeal under Regulations 24(1) and 24(2),

(f) include any other requirement that the inspector considers appropriate,

(g) state that if the person to whom the notice is addressed fails to take such measures as are specified in the notice within the time period specified in that notice, that person commits an offence, and

(h) be signed and dated by the inspector.

(3) A contravention notice may include directions—

(a) as to the measures to be taken to remedy any contravention or matter to which the notice relates, or to otherwise comply with the notice, and

(b) to bring the notice to the attention of any person who may be affected by it, or to the public generally.

(4) A person on whom a contravention notice has been served who is of the opinion that the contravention notice has been complied with shall confirm in writing to the inspector that the matters referred to in the notice have been so remedied.

(5) Where a person on whom a contravention notice has been served confirms in writing to the inspector in accordance with paragraph (4) that the matters referred to in the contravention notice have been remedied, the inspector shall, on being satisfied that the matters have been so remedied, within one month of receipt of such confirmation, give notice to the person concerned of compliance with the contravention notice.

(6) An inspector may—

(a) withdraw or amend a contravention notice at any time, or

(b) where no appeal is made or pending under Regulation 24(1), extend the period specified under paragraph (2) (d).

(7) Where there is no appeal under Regulation 24(1), the contravention notice shall take effect on the later of—

(a) the end of the period for making an appeal, or

(b) the day specified in the notice.

(8) A person shall comply with a contravention notice under this Regulation,

Appeal against Contravention Notice

24. (1) A person aggrieved by a contravention notice may, within 14 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served in and, in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(2) A person who appeals under paragraph (1) shall at the same time notify the Authority of the appeal and the grounds for the appeal and the Authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal.

(3) Where an appeal under paragraph (1) is taken, and the contravention notice is not cancelled, the notice shall take effect on the later of—

(a) the day next following the day on which the notice is confirmed on appeal or the appeal is withdrawn, or

(b) the day specified in the notice.

(4) Subject to paragraph (5), in the case of a product which the inspector does not consider to present a serious risk requiring rapid intervention as per Article 20 of EU Regulation 765/2008, the intended recipient of a measure referred to in Regulation 23(1) shall have the opportunity to make representations within 10 working days of first been advised of the inspectors intention, to the Authority in advance of the measure being taken.

(5) Where, due to the urgency of the measure referred to in Regulation 23(1), as justified in particular by public health, security or safety requirements, it is not possible to give the person concerned the opportunity to make representations in advance of the measure being taken, the Authority shall give such opportunity, as soon as may be, thereafter.

Prohibition Notice

25. (1) Where an inspector is of the opinion that at any place there is occurring or is likely to occur any activity relating to a product that involves or is likely to involve a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, the inspector may serve a notice (in these Regulations referred to as a "prohibition notice") on the person who is or who may reasonably be presumed to be in control of the activity concerned.

(2) A prohibition notice shall—

(a) state that the inspector is of the opinion referred to in paragraph (1),

(b) state the reason for that opinion,

(c) specify the activity in respect of which that opinion is held,

(d) where in the opinion of the inspector the activity involves a contravention, or likely contravention of any provision of the these Regulations, specify the provision,

(e) prohibit the carrying on of the activity concerned until the matters that give rise or are likely to give rise to the risk are remedied,

(f) inform the person concerned that he or she may appeal the prohibition notice to the District Court in accordance with Regulation 26(1),

(g) state that if the person to whom the prohibition notice is addressed fails to comply with the notice within the time period specified in the notice, that person commits an offence.and

(h) be signed and dated by the inspector.

(3) A prohibition notice may include directions—

(a) as to the measures to be taken to remedy any contravention or matter to which the notice relates, or to otherwise comply with the notice, and

(b) to bring the notice to the attention of any person who may be affected by it, or to the public generally.

(4) A prohibition notice shall take effect—

(a) when the notice is received by the person on whom it is served, or

(b) where an appeal is brought against the prohibition notice, on the day immediately following—

(i) the day on which the notice is confirmed on appeal or the appeal is withdrawn, or

(ii) the day specified in the notice,

whichever occurs later.

(5) A person on whom a prohibition notice has been served who is of the opinion that the matters referred to in the prohibition notice have been remedied by the date specified in the notice shall confirm in writing to the inspector that those matters have been so remedied.

(6) Where a person on whom a prohibition notice has been served confirms in writing to the inspector in accordance with paragraph (5) that the matters referred to in the prohibition notice have been remedied, the inspector shall, on being satisfied that the matters have been so remedied, within one month of receipt of such confirmation, give notice to the person concerned of such compliance with the prohibition notice.

(7) An inspector may at any time withdraw a prohibition notice if—

(a) the inspector is satisfied that the activity to which the notice relates no longer involves a serious risk to safety or health, or

(b) the inspector is satisfied that the notice was issued in error or is incorrect in some material respect.

(8) A person shall comply with a prohibition notice under this Regulation

Appeal against Prohibition Notice

26. (1) A person on whom a prohibition notice is served may, within 7 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(2) Where, on the hearing of an appeal under this Regulation, a prohibition notice is confirmed, notwithstanding Regulation 26(4), the judge by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition notice for such period as in the circumstances of the case the judge considers appropriate.

(3) A person who—

(a) brings an appeal under paragraph (1), or

(b) applies for the suspension of the operation of a prohibition notice under paragraph (2), shall at the same time notify the Authority of the appeal or the application, and the grounds for the appeal or application.

(4) The bringing of an appeal against a prohibition notice shall not have the effect of suspending the operation of the notice but the appellant may apply to the court to have the operation of the notice suspended until the appeal is disposed of and, on such application, the court may, if it thinks proper to do so, direct that the operation of the notice be suspended until the appeal is disposed of.

Order of the High Court

27. (1) Where a person contravenes a prohibition notice an inspector may apply ex parte to the High Court for an order prohibiting the continued contravention of the notice.

(2) The High Court may, upon an application under this Regulation, order the person on whom the prohibition notice concerned was served to cease doing such acts as the High Court directs.

Notice for information

28. (1) The Authority or a person prescribed under section 33 of the Act of 2005 or an inspector may, by notice (in these Regulations referred to as an "information notice") served on a person, require the person to give to the Authority, within such period and in such form as may be specified in the notice, any information specified in the notice that the Authority or the person prescribed under section 33 of the Act of 2005 or the inspector may reasonably require for the proper performance by it of its functions under these Regulations.

(2) The period specified in the information notice may be extended at the discretion of the Authority on the written application of the person on whom the notice is served.

(3) A person on whom an information notice is served may, within 7 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the district court district in which the notice was served and in determining the appeal the judge may, if he or she is satisfied that it is reasonable to do so, confirm, vary or cancel the notice.

(4) Where, on the hearing of an appeal under paragraph (3), an information notice is confirmed or varied, the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the notice for such period as in the circumstances of the case the judge considers appropriate.

(5) Subject to paragraph (6), a person on whom an information notice is served shall comply with the notice before the later of—

(a) the end of the period specified in the notice, or

(b) where the period referred to in subparagraph (a) is extended under paragraph (2), the end of that extended period.

(6) Where an appeal is brought under this Regulation, and the information notice to which the appeal relates is confirmed or varied or the appeal is withdrawn, the person on whom the notice is served shall comply with the notice before—

(a) the day immediately following the day on which the notice is confirmed or varied or the appeal is withdrawn,

(b) the end of the period specified in the notice, or

(c) where the operation of the notice has been suspended under paragraph (4), the end of the period of suspension,

whichever occurs latest.

Service of Notifications

29. (1) Subject to paragraphs (2) and (3), a notice or other document required or authorised to be served on, sent or given to a person shall be addressed to the person concerned by name and may be given to the person in one of the following ways—

(a) by delivering it to the person,

(b) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address,

(c) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address,

(d) if the person concerned has agreed to service of notices by means of an electronic communication (within the meaning assigned by section 2 of the Electronic Commerce Act 2000), service by such means, provided that there is a facility for confirming receipt of electronic communication and that such receipt has been confirmed; or

(e) if the address at which the person ordinarily resides cannot be ascertained by reasonable enquiry and the compliance notice relates to a premises, by delivering it to the premises or by affixing it in a conspicuous position on or near the premises.

(f) by any other means that may be prescribed.

(2) Where a notice or other document required or authorised to be served on, sent or given to a person is to be given to a person who is the owner or occupier of land or property and the name of the person cannot be ascertained by reasonable inquiry, it may be addressed to the person by using the words “the owner” or, as the case may require, “the occupier”

(3) For the purposes of this Regulation, a company within the meaning of the Companies Acts shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

Sharing information on the application of the Directive

30. (1) The Authority may provide information to any EU information network, the Commission or a competent authority of another Member State for the purpose of sharing information related to the application of the Directive.

(2) The Authority may, in the interest of the protection of safety, take such measures as it considers appropriate to bring to the attention of the public, any matter of concern arising from the requirements of these Regulations.

PART 6

OFFENCES AND PENALTIES

Offences

31. (1) A person who contravenes a provision or requirement of Regulation 4, 5, 6, 7, 8, 10 or 14 commits an offence.

(2) A person who contravenes a requirement of a notice or other measure made under Regulations 22, 23, 25 or 28 commits an offence.

(3) A person who, in relation to the CE marking or any document required for the purposes of these Regulations—

(a) forges or counterfeits any such document,

(b) gives or signs a document or makes a marking knowing it to be false in any material particular,

(c) knowingly utters or uses a marking or document so forged or counterfeited, or which is false as aforesaid,

(d) knowingly utters or uses as applying to any person or product a marking or document which does not so apply,

(e) knowingly connives at any such forging, counterfeiting, giving, signing, uttering or using,

(f) knowingly makes a false entry in any such document which is so required to be kept, served or sent,

(g) knowingly uses any such false entry, or

(h) knowingly has, without lawful authority, a forged marking or document or an altered marking or document in his or her possession, commits an offence.

(4) Any person who obstructs or interferes with an inspector or a member of the Garda Síochána in the course of exercising a power conferred on him or her by these Regulations or a

warrant under Regulation 21(7) or impedes the exercise by the inspector or member, as the case may be, of such power, or fails or refuses to comply with a request or requirement of, or to answer a question asked by, an inspector or such a member pursuant to a power conferred by these Regulations, or in purported compliance with such request or requirement, or who in answer to such question gives information to the inspector or member that he or she knows to be false or misleading in any material respect, commits an offence.

(5) A person who falsely represents himself or herself to be an inspector commits an offence.

(6) A person who, at any time during the period of 3 months immediately following the affixing of a notice in accordance with Regulation 29(1)(e), removes, alters, damages or defaces the notice without lawful authority commits an offence.

(7) A person who states to the Authority that another person has committed an offence under this Regulation or has failed to comply with a provision of these Regulations, knowing the statement to be false, commits an offence.

(8) A person who, in purported compliance with a requirement in an information notice, furnishes information to the Authority that he or she knows to be false or misleading in a material respect commits an offence.

Penalties

32. (1) A person guilty of an offence under Regulation 31 shall be liable—

(a) on summary conviction, to a fine not exceeding €5,000 or imprisonment for a term not exceeding 6 months or both, or

(b) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.

(2) Where a person is convicted of an offence under these Regulations in proceedings brought by the Authority, or instituted following an investigation by the Authority, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the Authority the costs and expenses, measured by the court, incurred by the Authority in relation to the investigation, detection and prosecution of the offence, including the costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisers engaged by the Authority.

Offences by Bodies Corporate

33. Where an offence under these Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a person being a director, manager, secretary or other officer of the body

corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate commits an offence and shall be liable to be proceeded against and punished as if he or she had committed the first-mentioned offence.

Prosecution of Offences

34. (1) Subject to paragraph (2), summary proceedings in relation to an offence under these Regulations may be brought and prosecuted by the Authority.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under Regulation 29 may be instituted at any time within 12 months from the date on which the offence was committed or alleged to have been committed.

PART 7

MISCELLANEOUS

Appeal to Circuit Court from certain orders of District Court

35. For the avoidance of doubt, an order of the District Court confirming, varying or cancelling a notice under Regulation 23, 25 or 28 is a decision of a judge of the District Court for the purposes of section 84 of the Courts of Justice Acts 1924.

Notice or Direction to be in Writing

36. Any notice or direction under these Regulations shall be in writing.

Transitional provisions

37. (1) The making available on the market of products which are in conformity with the Regulations of 1999 and which were placed on the market before 20 April 2016 continues to be lawful.

(2) Certificates issued under the Regulations of 1999 shall be valid under these Regulations for products as described in paragraph (1).

Revocation

38. The European Communities (Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres) Regulations, (S.I. No. 83 of 1999) are revoked with effect from the 19th April 2016.

SCHEDULE 1

ANNEX I TO THE DIRECTIVE

CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

1. Equipment-group I

(a) Equipment category M 1 comprises equipment designed and, where necessary, equipped with additional special means of protection to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines endangered by firedamp and/or combustible dust.

Equipment in this category is required to remain functional, even in the event of rare incidents relating to equipment, with an explosive atmosphere present, and is characterised by means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in point 2.0.1 of Annex II.

(b) Equipment category M 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a high level of protection.

Equipment in this category is intended for use in underground parts of mines as well as those parts of surface installations of such mines likely to be endangered by firedamp and/or combustible dust.

This equipment is intended to be de-energised in the event of an explosive atmosphere.

The means of protection relating to equipment in this category assure the requisite level of protection during normal operation and also in the case of more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

Equipment in this category must comply with the supplementary requirements referred to in point 2.0.2 of Annex II.

2. Equipment-group II

(a) Equipment category 1 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and ensuring a very high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by mixtures of air and gases, vapours or mists or by air/dust mixtures are present continuously, for long periods or frequently.

Equipment in this category must ensure the requisite level of protection, even in the event of rare incidents relating to equipment, and is characterised by means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in point 2.1 of Annex II.

(b) Equipment category 2 comprises equipment designed to be capable of functioning in conformity with the operational parameters established by the manufacturer and of ensuring a high level of protection.

Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mists or air/dust mixtures are likely to occur occasionally.

SCHEDULE 2

ANNEX II TO THE DIRECTIVE

ESSENTIAL HEALTH AND SAFETY REQUIREMENTS RELATING TO THE DESIGN AND CONSTRUCTION OF EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

Preliminary observations

A. Technological knowledge, which can change rapidly, must be taken into account as far as possible and be utilised immediately.

B. For devices the essential requirements shall apply only in so far as they are necessary for the safe and reliable functioning and operation of those devices with respect to the risks of explosion.

1. Common requirements for equipment and protective systems

1.0. General requirements

1.0.1. Principles of integrated explosion safety

Equipment and protective systems intended for use in potentially explosive atmospheres must be designed from the point of view of integrated explosion safety.

In this connection, the manufacturer must take measures:

— above all, if possible, to prevent the formation of explosive atmospheres which may be produced or released by equipment and by protective systems themselves,

— to prevent the ignition of explosive atmospheres, taking into account the nature of every electrical and non-electrical source of ignition,

— should an explosion nevertheless occur which could directly or indirectly endanger persons and, as the case may be, domestic animals or property, to halt it immediately and to limit the range of explosion flames and explosion pressures to a sufficient level of safety or both

1.0.2. Equipment and protective systems must be designed and manufactured after due analysis of possible operating faults in order as far as possible to preclude dangerous situations. Any misuse which can reasonably be anticipated must be taken into account.

1.0.3. Special checking and maintenance conditions

Equipment and protective systems subject to special checking and maintenance conditions must be designed and constructed with such conditions in mind.

1.0.4. Surrounding area conditions

Equipment and protective systems must be so designed and constructed as to be capable of coping with actual or foreseeable surrounding area conditions.

1.0.5. Marking

All equipment and protective systems must be marked legibly and indelibly with the following minimum particulars:

— name and address of the manufacturer,

— CE marking, (see Annex II to Regulation (EC) No 765/2008),

— designation of series or type,

— serial number, if any,

— year of construction,

— the specific marking of explosion protection followed by the symbol of the equipment group and category,

— for equipment-group II, the letter “G” (concerning explosive atmospheres caused by gases, vapours or mists),

and

the letter “D” (concerning explosive atmospheres caused by dust), or both such letters.

Furthermore, where necessary, they must also be marked with all information essential to their safe use.

1.0.6. Instructions

(a) All equipment and protective systems must be accompanied by instructions, including at least the following particulars:

— a recapitulation of the information with which the equipment or protective system is marked, except for the serial number referred to in paragraph 1.0.5. together with any appropriate additional information to facilitate maintenance and should include the address of the importer, repairer;

— instructions for safe:

— putting into service,

— use,

— assembling and dismantling,

— maintenance (servicing and emergency repair),

— installation,

— adjustment;

— where necessary, an indication of the danger areas in front of pressure-relief devices;

— where necessary, training instructions;

— details which allow a decision to be taken beyond any doubt as to whether an item of equipment in a specific category or a protective system can be used safely in the intended area under the expected operating conditions;

— electrical and pressure parameters, maximum surface temperatures and other limit values;

— where necessary, special conditions of use, including particulars of possible misuse which experience has shown might occur;

— where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

(b) The instructions must contain the drawings and diagrams necessary for the putting into service, maintenance, inspection, checking of correct operation and, where appropriate, repair of the equipment or protective system, together with all useful instructions, in particular with regard to safety.

(c) Literature describing the equipment or protective system must not contradict the instructions with regard to safety aspects.

1.1. Selection of materials

1.1.1. The materials used for the construction of equipment and protective systems must not trigger off an explosion, taking into account foreseeable operational stresses.

1.1.2. Within the limits of the operating conditions laid down by the manufacturer, it must not be possible for a reaction to take place between the materials used and the constituents of the potentially explosive atmosphere which could impair explosion protection.

1.1.3. Materials must be so selected that predictable changes in their characteristics and their compatibility in combination with other materials will not lead to a reduction in the protection afforded; in particular, due account must be taken of the material’s corrosion and wear resistance, electrical conductivity, impact strength, ageing resistance and the effects of temperature variations.

1.2. Design and Construction

1.2.1. Equipment and protective systems must be designed and constructed with due regard to technological knowledge of explosion protection so that they can be safely operated throughout their foreseeable lifetime.

1.2.2. Components to be incorporated into or used as replacements in equipment and protective systems must be so designed and constructed that they function safely for their intended purpose of explosion protection when they are installed in accordance with the manufacturer's instructions.

1.2.3. Enclosed structure and prevention of leaks

Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only. If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that developing gases or dusts cannot give rise to explosive atmospheres outside the equipment. Points where materials are introduced or drawn off must, as far as possible, be designed and equipped so as to limit escapes of flammable materials during filling or draining.

1.2.4. Dust deposits

Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited. In general, dust deposits must be limited where possible. Equipment and protective systems must be easily cleanable. The surface temperatures of equipment parts must be kept well below the glow temperature of the deposit dust. The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

1.2.5. Additional means of protection

Equipment and protective systems which may be exposed to certain types of external stresses must be equipped, where necessary, with additional means of protection. Equipment must withstand relevant stresses, without adverse effect on explosion protection.

1.2.6. Safe opening

If equipment and protective systems are in a housing or a locked container forming part of the explosion protection itself, it must be possible to open such housing or container only with a special tool or by means of appropriate protection measures.

1.2.7. Protection against other hazards

Equipment and protective systems must be so designed and manufactured as to:

(a) avoid physical injury or other harm which might be caused by direct or indirect contact;

(b) assure that surface temperatures of accessible parts of radiation which would cause a danger, are not produced;

(c) eliminate non-electrical dangers which are revealed by experience;

(d) assure that foreseeable conditions of overload shall not give rise to dangerous situations.

Where, for equipment and protective systems, the risks referred to in this paragraph are wholly or partly covered by other Community Directives, these Regulations shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of those specific Directives or these Regulations where appropriate.

1.2.8. Overloading of equipment

Dangerous overloading of equipment must be prevented at the design stage by means of integrated measurement, regulation and control devices, such as over-current cut-off switches, temperature limiters, differential pressure switches, flowmeters, time-lag relays, overspeed monitors and similar types of monitoring devices or both such switches, limiters, flowmeters, relays and monitors.

1.2.9. Flameproof enclosure systems

If parts which can ignite an explosive atmosphere are placed in an enclosure, measures must be taken to ensure that the enclosure withstands the pressure developed during an internal explosion of an explosive mixture and prevents the transmission of the explosion to the explosive atmosphere surrounding the enclosure.

1.3. Potential ignition sources

1.3.1. Hazards arising from different ignition sources

Potential ignition sources such as sparks, flames, electric arcs, high surface temperatures, acoustic energy, optical radiation, electro-magnetic waves and other ignition sources must not occur.

1.3.2. Hazards arising from static electricity

Electrostatic charges capable of resulting in dangerous discharges must be prevented by means of appropriate measures.

1.3.3. Hazards arising from stray electric and leakage currents

Stray electric and leakage currents in conductive equipment parts which could result in, for example, the occurrence of dangerous corrosion, overheating of surfaces or sparks capable of provoking an ignition must be prevented.

1.3.4. Hazards arising from overheating

Overheating caused by friction or impacts occurring, for example, between materials and parts in contact with each other while rotating or through the intrusion of foreign bodies must, as far as possible, be prevented at the design stage.

1.3.5. Hazards arising from pressure compensation operations

Equipment and protective systems must be so designed or fitted with integrated measuring, control and regulation devices that pressure compensations arising from them do not generate shock waves or compressions which may cause ignition.

1.4. Hazards arising from external effects

1.4.1. Equipment and protective systems must be so designed and constructed as to be capable of performing their intended function in full safety, even in changing environmental conditions and in the presence of extraneous voltages, humidity, vibrations, contamination and other external effects, taking into account the limits of the operating conditions established by the manufacturer.

1.4.2. Equipment parts used must be appropriate to the intended mechanical and thermal stresses and capable of withstanding attack by existing or foreseeable aggressive substances.

1.5. Requirements in respect of safety-related devices

1.5.1. Safety devices must function independently of any measurement or control devices required for operation. As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur. For electrical circuits the fail-safe principle is to be applied in general. Safety-related switching must in general directly actuate the relevant control devices without intermediate software command.

1.5.2. In the event of a safety device failure, equipment and protective systems shall, wherever possible, be secured.

1.5.3. Emergency stop controls of safety devices must, as far as possible, be fitted with restart lockouts. A new start command may take effect on normal operation only after the restart lockouts have been intentionally reset.

1.5.4. Control and display units

Where control and display units are used, they must be designed in accordance with ergonomic principles in order to achieve the highest possible level of operating safety with regard to the risk of explosion.

1.5.5. Requirements in respect of devices with a measuring function for explosion protection

In so far as they relate to equipment used in explosive atmospheres, devices with a measuring function must be designed and constructed so that they can cope with foreseeable operating requirements and special conditions of use.

1.5.6. Where necessary, it must be possible to check the reading accuracy and serviceability of devices with a measuring function.

1.5.7. The design of devices with a measuring function must incorporate a safety factor which ensures that the alarm threshold lies far enough outside the explosion and ignition limits or either of them of the atmospheres to be registered, taking into account, in particular, the

operating conditions of the installation and possible aberrations in the measuring system.1.5.8. Risks arising from software

In the design of software-controlled equipment, protective systems and safety devices, special account must be taken of the risks arising from faults in the programme.

1.6. Integration of safety requirements relating to the system

1.6.1. Manual override must be possible in order to shut down the equipment and protective systems incorporated within automatic processes which deviate from the intended operating conditions, provided that this does not compromise safety.

1.6.2. When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard. This does not apply to electrochemically-stored energy.

1.6.3. Hazards arising from power failure

Where equipment and protective systems can give rise to a spread of additional risks in the event of a power failure, it must be possible to maintain them in a safe state of operation independently of the rest of the installation.

1.6.4. Hazards arising from connections

Equipment and protective systems must be fitted with suitable cable and conduit entries. When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface must be safe.

1.6.5. Placing of warning devices as parts of equipment

Where equipment or protective systems are fitted with detection or alarm devices for monitoring the occurrence of explosive atmospheres, the necessary instructions must be provided to enable them to be provided at the appropriate places.

2. Supplementary requirements in respect of equipment

2.0. Requirements applicable to equipment in category M of equipment-group I.

2.0.1. Requirements applicable to equipment in category M 1 of equipment-group I.

2.0.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in the event of rare incidents relating to equipment.

Equipment must be equipped with means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

Where necessary, this equipment must be equipped with additional special means of protection. It must remain functional with an explosive atmosphere present.

2.0.1.2. Where necessary, equipment must be so constructed that no dust can penetrate it.

2.0.1.3. The surface temperatures of equipment parts must be kept clearly below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.0.1.4. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment. If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.0.2. Requirements applicable to equipment in category M 2 of equipment-group I.

2.0.2.1. Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions. The equipment is intended to be de-energised in the event of an explosive atmosphere.

2.0.2.2. Equipment must be so designed that the opening of equipment parts which may be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.0.2.3. The requirements regarding explosion hazards arising from dust applicable to category M 1 must be applied.

2.1. Requirements applicable to equipment in category 1 of equipment-group II.

2.1.1. Explosive atmospheres caused by gases, vapours or hazes.

2.1.1.1. Equipment must be so designed and constructed that sources of ignition do not become active, even in event of rare incidents relating to equipment. It must be equipped with means of protection such that:

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.1.2. For equipment with surfaces which may heat up, measures must be taken to ensure that the stated maximum surface temperatures are not exceeded even in the most unfavourable circumstances.

Temperature rises caused by heat build-ups and chemical reactions must also be taken into account.

2.1.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active or intrinsically safe conditions. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment. If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.1.2. Explosive atmospheres caused by air/dust mixtures.

2.1.2.1. Equipment must be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rate incidents relating to equipment. It must be equipped with means of protection such that

— either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,

— or, the requisite level of protection is ensured in the event of two faults occurring independently of each other.

2.1.2.2. Where necessary, equipment must be so designed that dust can enter or escape from the equipment only at specifically designated points. This requirement must also be met by cable entries and connecting pieces.

2.1.2.3. The surface temperatures of equipment parts must be kept well below the ignition temperature of the foreseeable air/dust mixtures in order to prevent the ignition of suspended dust.

2.1.2.4. With regard to the safe opening of equipment parts, requirement 2.1.1.3 applies.

2.2. Requirements for category 2 of equipment-group II.

2.2.1. Explosive atmospheres caused by gases, vapours or mists.

2.2.1.1. Equipment must be so designed and constructed as to prevent ignition sources arising, even in the event of frequently occurring disturbances or equipment operating faults, which normally have to be taken into account.

2.2.1.2. Equipment parts must be so designed and constructed that their stated surface temperatures are not exceeded, even in the case of risks arising from abnormal situations anticipated by the manufacturer.

2.2.1.3. Equipment must be so designed that the opening of equipment parts which might be sources of ignition is possible only under non-active conditions or via appropriate interlocking systems. Where it is not possible to render equipment non-active, the manufacturer must affix a warning label to the opening part of the equipment.

2.2.2. Explosive atmospheres caused by air/dust mixtures.

2.2.2.1. Equipment must be designed and constructed so that ignition of air/dust mixtures is prevented, even in the event of frequently occurring disturbances or equipment operating faults which normally have to be taken into account.

2.2.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.2.2.3. With regard to protection against dust, requirement 2.1.2.2 applies.

2.2.2.4. With regard to the safe opening of equipment parts, requirement 2.2.1.3 applies.

2.3. Requirements applicable to equipment in category 3 of equipment-group II.

2.3.1. Explosive atmospheres caused by gases, vapours or mists.

2.3.1.1. Equipment must be so designed and constructed as to prevent foreseeable ignition sources which can occur during normal operation.

2.3.1.2. Surface temperatures must not exceed the stated maximum surface temperatures under intended operating conditions. Higher temperatures in exceptional circumstances may be allowed only if the manufacturer adopts special additional protective measures.

2.3.2. Explosive atmospheres caused by air/dust mixtures.

2.3.2.1. Equipment must be so designed and constructed that air/dust mixtures cannot be ignited by foreseeable ignition sources likely to exist during normal operation.

2.3.2.2. With regard to surface temperatures, requirement 2.1.2.3 applies.

2.3.2.3. Equipment, including cable entries and connecting pieces, must be so constructed that, taking into account the size of its particles, dust can neither develop explosive mixtures with air nor form dangerous accumulation inside the equipment.

3. Supplementary requirements in respect of protective systems

3.0. General requirements.

3.0.1. Protective systems must be dimensioned in such a way as to reduce the effects of an explosion to a sufficient level of safety.

3.0.2. Protective systems must be designed and capable of being positional in such a way that explosions are prevented from spreading through dangerous chain reactions or flashover and incipient explosions do not become detonations.

3.0.3. In the event of a power failure, protective systems must retain their capacity to function for a period sufficient to avoid a dangerous situation.

3.0.4. Protective systems must not fail due to outside interference.

3.1. Planning and design.

3.1.1. Characteristics of materials

With regard to the characteristics of materials, the maximum pressure and temperature to be taken into consideration at the planning stage are the expected pressure during an explosion occurring under extreme operating conditions and the anticipated heating effect of the flame.

3.1.2. Protective systems designed to resist or contain explosions must be capable of withstanding the shock wave produced without losing system integrity.

3.1.3. Accessories connected to protective systems must be capable of withstanding the expected maximum explosion pressure without losing their capacity to function.

3.1.4. The reactions caused by pressure in peripheral equipment and connected pipe-work must be taken into consideration in the planning and design of protective systems.

3.1.5. Pressure relief systems.

If it is likely that stresses on protective systems will exceed their structural strength, provision must be made in the design for suitable pressure-relief devices which do not endanger persons in the vicinity.

3.1.6. Explosion suppression systems.

Explosion suppression systems must be so planned and designed that they react to an incipient explosion at the earliest possible stage in the event of an incident and counteract it to best effect, with due regard to the maximum rate of pressure increase and the maximum explosion pressure.

3.1.7. Explosion decoupling systems.

Decoupling systems intended to disconnect specific equipment as swiftly as possibly in the event of incipient explosions by means of appropriate devices must be planned and designed so as to remain proof against the transmission of internal ignition and to retain their mechanical strength under operating conditions.

3.1.8. Protective systems must be capable of being integrated into a circuit with a suitable alarm threshold so that, if necessary, there is cessation of product feed and output and shutdown of equipment parts which can no longer function safely.

4**. Minimum criteria to be taken into account by Member States for the notification of bodies**

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems, or devices which they inspect, nor the authorised representative of any of these parties. They shall become involved neither directly nor as authorised representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

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

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

4. The staff responsible for inspection shall have:

   — sound technical and professional training,

   — satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;

   — the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

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

6. The body shall take out liability insurance unless its liability is assumed by the State in accordance with national law or the Member State itself is directly responsible for the tests.

7. The staff of the body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks (except vis-à-vis the competent administrative authorities of the State in which its activities are carried out) under these Regulations or any provision of national law giving effect to it.

SCHEDULE 3

ANNEX III TO THE DIRECTIVE

MODULE B EU-TYPE EXAMINATION

1. EU-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 this Directive that apply to it.

2. EU-type examination shall be carried out with the examination of a specimen, representative of the production envisaged, of the complete product (production type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

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

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

(c) the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of this Directive 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 at least the following elements:

i) a general type-description;

ii) design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;

iii) descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;

iv) a list of the standards referred to in these Regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of these Regulations where the standards referred to have not been applied;

v) results of design calculations made, examinations carried out, etc.;

vi) test reports.

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

4. The notified body shall:

4.1. examine the technical documentation, 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, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.2. 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, these have been applied correctly;

4.3 carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential health and safety requirements of this Directive;

4.4 agree with the applicant the location where the examinations and necessary tests shall 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 this Directive that apply to the product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That 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 EU-type examination certificate may have one or more annexes attached.

The EU-type examination 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 this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself appraised 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 this Directive, 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 EU-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential health and safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall

require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-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 authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

9. The manufacturer shall keep a copy of the EU-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.

SCHEDULE 4

ANNEX IV TO THE DIRECTIVE

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 EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. The manufacturer shall operate an approved quality system for production, final equipment inspection and testing as specified in paragraph 3 and shall be subject to monitoring as specified in paragraph 4.

3. Quality system.

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

The application shall include:

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

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

(c) all relevant information for the product category envisaged,

(d) the documentation concerning the quality system,

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2 The quality system shall ensure compliance of the equipment with the type as described in the EU-type-examination certificate and with the requirements of these Regulations which apply to them. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation must permit a consistent interpretation of quality programmes, plans, manuals and records.

It shall contain, in particular, an adequate description of

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

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

— the examinations and tests which 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, reports on the qualifications of the personnel concerned, etc.;

— the means to monitor the achievement of the required equipment 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 paragraph 3.2.

It shall presume conformity with these requirements in respect of quality systems that comply with the corresponding specifications of the relevant harmonised standard..

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 this Directive. 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(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive 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 uphold the system 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:

(a) the quality system documentation,

(b) 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. CE marking, EU declaration of conformity and attestation of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall accompany every product, other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

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

(a) the documentation referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved,

(c) 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 authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority 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

SCHEDULE 5

ANNEX V TO THE DIRECTIVE

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 and 5 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 EU-type examination certificate and satisfy the requirements of this Directive 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 EU-type examination certificate and with the requirements of this Directive 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 EU-type examination certificate and with the appropriate requirements of this Directive.

The examinations and tests to check the conformity of the products with the appropriate requirements shall be carried out by examination and testing of every product as specified in point 4.

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 equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

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. CE marking, EU declaration of conformity and attestation of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual product other than a component that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall accompany every product other than a component.

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 other than components.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6 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.

7. 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 point 2.

SCHEDULE 6

ANNEX VI TO THE DIRECTIVE

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 EU-type examination certificate and satisfy the requirements of this Directive 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 EU-type examination certificate and with the requirements of this Directive 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 type described in the EU- type examination certificate and with the corresponding requirements of this Directive. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.

4. CE marking, EU declaration of conformity and attestation of conformity

4.1. The manufacturer shall affix the CE marking to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall accompany every product, other than a component.

4.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

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.

SCHEDULE 7

ANNEX VII TO THE DIRECTIVE.

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 EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

2. The manufacturer shall operate an approved quality system for the final inspection and testing of equipment as specified in paragraph 3 below and shall be subject to surveillance as specified in paragraph 4 below.

3. Quality system.

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

The application shall include:

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

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

(c) all relevant information for the product category envisaged,

(d) the documentation concerning the quality system, and

(e) the technical documentation of the approved type and a copy of the EU-type examination certificate.

3.2. The quality system shall ensure compliance of the products with the type described in the EU-type examination certificate and with the applicable requirements of this Directive.

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 instruments. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall contain, in particular, 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 which will be carried out after manufacture;

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

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

— quality 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 paragraph 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 relevant harmonised standard.

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 this Directive. 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(e) in order to verify the manufacturer's ability to identify the relevant requirements of this Directive 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 examination 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 ensure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

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

— 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. CE marking, EU declaration of conformity and attestation of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall accompany every product other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

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

(a) the documentation referred to in point 3.1,

(b) the information relating to the change referred to in point 3.5, as approved,

(c) 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 authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority 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.

SCHEDULE 8

ANNEX VIII TO THE DIRECTIVE

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 this Directive 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 contain at least the following elements:

(a) a general description of the product,

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

(e) results of design calculations made, examinations carried out, etc., and

(f) 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 this Directive that apply to them.

4. CE marking, EU declaration of conformity and attestation of conformity

4.1. The manufacturer shall affix the CE marking to each individual product other than a component that satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall accompany every product other than a component.

4.3. The manufacturer shall draw up a written attestation of conformity for each component model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

5. Authorised representative

The manufacturers 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.

SCHEDULE 9

ANNEX IX TO THE DIRECTIVE

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 this Directive that apply to it.

2. Technical documentation

2.1. 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 contain at least the following elements:

(a) a general description of the product,

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,

(c) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

(d) a list of the harmonised standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

(e) results of design calculations made, examinations carried out, etc., and

(f) test reports.

2.2. 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 this Directive.

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 equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard 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. CE marking, EU declaration of conformity and attestation of conformity

5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 4, the latter"s identification number to each product other than a component that satisfies the applicable requirements of this Directive.

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

A copy of the EU declaration of conformity shall accompany every product, other than a component.

5.3. The manufacturer shall draw up a written attestation of conformity and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. Authorised representative

The manufacturers obligations set out in points 2.2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

SCHEDULE 10

ANNEX X TO THE DIRECTIVE.

EU DECLARATION OF CONFORMITY (No XXXX)

1. Product model/product (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, his authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of product allowing traceability; it may, where necessary for the identification of the product, include an image):

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

6. References to the relevant harmonised standards used or references to the other technical 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):

GIVEN under my Official Seal,