



STATUTORY INSTRUMENTS.

S.I. No. 230 of 2017

EUROPEAN UNION (EQUIPMENT AND PROTECTIVE SYSTEMS
INTENDED FOR USE IN POTENTIALLY EXPLOSIVE
ATMOSPHERES) REGULATIONS 2017

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INTENDED FOR USE IN POTENTIALLY EXPLOSIVE
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ARRANGEMENT OF REGULATIONS

PART 1

CITATION, INTERPRETATION

1. Citation.
2. Interpretation.
3. Designation
4. Application.
5. Making available on the market and putting into service.
6. Essential health and safety requirements.

PART 2

OBLIGATIONS OF ECONOMIC OPERATORS

7. Obligations of manufacturers.
8. Authorised representatives.
9. Obligations of importers.
10. Obligations of distributors.
11. Cases in which obligations of manufacturers apply to importers and distributors.
12. Identification of economic operators.

PART 3

CONFORMITY OF PRODUCTS

13. Presumption of conformity on the basis of harmonised standards.
14. Conformity assessment procedures.
15. EU declaration of conformity.
16. General principles of the CE marking.
17. Rules and conditions for affixing the CE marking and other markings.

PART 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

18. Notified bodies.
19. Application for notification by conformity assessment bodies.
20. Notification of conformity assessment bodies.
21. Changes to notifications.
22. Subsidiaries of and subcontracting by notified bodies.
23. Operational obligations of notified bodies.
24. Appeal against decisions of notified bodies.
25. Information obligation on notified bodies.

PART 5

MARKET SURVEILLANCE, SAFEGUARD PROCEDURE

26. Market surveillance.
27. Procedure for dealing with products presenting a risk at national level.
28. Safeguard procedure.
29. Compliant products which present a risk.
30. Formal non-compliance.

PART 6

POWERS OF THE MARKET SURVEILLANCE AUTHORITY

31. General.
32. Powers of inspectors.
33. Measures entailing refusal or restriction.
34. Contravention notice.
35. Appeal against contravention notice.
36. Prohibition notice.
37. Appeal against prohibition notice.
38. Order of the High Court.
39. Information notice.
40. Service of notifications.

41. Sharing information on the application of the Directive.

PART 7

OFFENCES AND PENALTIES

42. Offences.

43. Penalties.

44. Offences by bodies corporate.

45. Prosecution of offences.

PART 8

MISCELLANEOUS

46. Appeal to Circuit Court from certain orders of District Court.

47. Notice or direction to be in writing.

48. Immunity.

49. Indemnification.

50. Restrictions on the disclosure of information.

51. Transitional.

52. Revocation.

SCHEDULE 1

TEXT OF ANNEX I TO THE DIRECTIVE

Criteria determining the classification of equipment-groups into categories.

SCHEDULE 2

TEXT OF 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.

SCHEDULE 3

TEXT OF ANNEX III TO THE DIRECTIVE

Module B: EU-type examination.

SCHEDULE 4

TEXT OF ANNEX IV TO THE DIRECTIVE

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

SCHEDULE 5

TEXT OF ANNEX V TO THE DIRECTIVE

Module F: Conformity to type based on product verification.

SCHEDULE 6

TEXT OF ANNEX VI TO THE DIRECTIVE

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

SCHEDULE 7

TEXT OF ANNEX VII TO THE DIRECTIVE

Module E: Conformity to type based on product quality assurance.

SCHEDULE 8

TEXT OF ANNEX VIII TO THE DIRECTIVE

Module A: Internal production control.

SCHEDULE 9

TEXT OF ANNEX IX TO THE DIRECTIVE

Module G: Conformity based on unit verification.

SCHEDULE 10

TEXT OF ANNEX X TO THE DIRECTIVE

EU declaration of conformity.

SCHEDULE 11

TEXT OF ANNEX XII TO THE DIRECTIVE

Correlation Table.

EUROPEAN UNION (EQUIPMENT AND PROTECTIVE SYSTEMS
INTENDED FOR USE IN POTENTIALLY EXPLOSIVE
ATMOSPHERES) REGULATIONS 2017

I, MARY MITCHELL O'CONNOR, Minister for 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) (as amended by section 2 of the European Communities Act 2007 (No. 18 of 2007) and for the purpose of giving effect to Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014¹ and of giving further effect to Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008², hereby make the following regulations:

PART 1

CITATION, INTERPRETATION

Citation

1. These Regulations may be cited as the European Union (Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres) Regulations 2017.

Interpretation

2. (1) In these Regulations—

“accreditation” has the meaning assigned to it 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 (No. 10 of 2005);

“authorised representative” means any natural or legal person established within the European Economic Area who has received a written mandate from a manufacturer to act on its behalf in relation to specified tasks;

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

“Companies Acts” means the Companies Act 2014 (No. 38 of 2014) or, as the context may require, the legislation repealed by s. 4 of the Companies Act 2014;

“competent authority” means—

¹OJ No. L 96, 29.3.2014, p.309.

²OJ No. L. 218, 13.8.2008, p.30.

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 2nd June, 2017.*

- (a) in the State, the market surveillance authority, or
- (b) in another Member State, any authority or body to whom functions have been assigned as a competent authority or a market surveillance authority, for the purposes of the Directive;

“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 the Directive or these Regulations relating to a product have been fulfilled;

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

“contravention notice” means the notice provided for in Regulation 34;

“Coroners Acts 1962 and 2005” means the Coroners Act 1962 (No. 9 of 1962) as amended by the Coroners (Amendment) Act 2005 (No. 33 of 2005);

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

“Directive 94/9/EC” means Directive 94/9/EC of the European Parliament and of the Council of 23 March 1994³;

“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 operator” means a manufacturer, authorised representative, importer or 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 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 Annex I to the Directive the text of which is set out in Schedule 1 to 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 set out in Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations;

³OJ No. L 100, 19.4.1994, p.1.

“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 Annex I to the Directive, the text of which is set out in Schedule 1 to these Regulations;

“EU declaration of conformity” means a declaration of conformity drawn up in accordance with Regulation 15;

“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” has the meaning assigned to it in point (c) of Point 1 of Article 2 of Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012⁴;

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

“information notice” means the notice provided for in Regulation 39;

“inspector” has the meaning assigned to it in Regulation 31(2);

“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 market of the European Economic Area 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 trademark or uses it for his own purposes;

“market surveillance authority” means the authority designated as a market surveillance authority under Regulation 3;

“means of transport” means 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,

⁴OJ No. L 316, 14.11.2012, p.12.

by public road or rail networks or by water but does not include vehicles intended for use in a potentially explosive atmosphere;

“Member State” means a state which is a contracting party to the Agreement on the European Economic Area signed in Oporto on 2 May 1992;

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

“notified body” means—

(a) in the State, a conformity assessment body notified by the notifying authority pursuant to Regulation 18, and

(b) in another Member State, a conformity assessment body notified by the relevant notifying authority pursuant to the Directive;

“notifying authority” means the authority designated as the notifying authority in the State under Regulation 3 and in another Member State the authority designated as notifying authority pursuant to the Directive;

“Official Journal” means the Official Journal of the European Union;

“person in charge” means, in relation to a place—

(a) the person under whose direction and control the activities at that place are being conducted, or

(b) the person whom the inspector has reasonable grounds for believing is in control of that place;

“placing on the market” means the first making available of a product on the market of the European Economic Area;

“premises of an economic operator” means any premises owned or being used by an economic operator;

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

“product” means the items specified in Regulation 4(1)(a), (b) or (c);

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

“prohibition notice” means the notice provided for in Regulation 36;

“putting into service” means the first use of a product by its user;

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

“Regulation (EC) No. 765/2008” means Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 996/93;

“Regulations of 1999” means the European Communities (Equipment and 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 European 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 which is used in these Regulations and which 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) References to the repealed Directive 94/9/EC shall be construed in existing laws, regulations and administrative provisions of the State as references to the Directive and shall be read in accordance with the correlation table in Annex XII, the text of which is set out in Schedule 11 to these Regulations.

Designation

3. For the purposes of the Directive and these Regulations—

- (a) the Health and Safety Authority is designated as the market surveillance authority, and
- (b) the Minister is designated as the notifying authority.

Application

4. (1) Subject to paragraph (2) these Regulations apply to—

- (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 do 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 1989⁵ 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,
- (g) the equipment covered by point (b) of Article 346(1) of the Treaty on the Functioning of the European Union.

Making available on the market and putting into service

5. (1) Subject to paragraph (2) a person shall not make available on the market or put into service a product unless it satisfies the requirements of the Directive or these Regulations when properly installed and maintained and used for the purpose for which it is intended.

(2) Paragraph (1) shall not prevent a person from showing a product which does not comply with the Directive or these Regulations at a trade fair, exhibition or demonstration, provided that—

- (a) a visible sign clearly indicates that the product does not comply with the Directive or these Regulations and that it is not for sale until it has been brought into conformity, and
- (b) adequate safety measures are taken during demonstrations to ensure the protection of persons.

Essential health and safety requirements

6. Products shall satisfy the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations, account being taken of their intended use.

PART 2

OBLIGATIONS OF ECONOMIC OPERATORS

Obligations of manufacturers

7. A manufacturer shall—

⁵OJ No. L 399, 30.12.89, p.18.

- (a) ensure that the product placed on the market by the manufacturer or used for the manufacturer's own purposes, has been designed and manufactured in accordance with the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations,
- (b) draw up the technical documentation referred to in Annexes III to IX to the Directive, the text of which is set out in Schedules 3 to 9 to these Regulations and carry out the relevant conformity assessment procedure referred to in Regulation 14 or have it carried out,
- (c) in a case where compliance of a product, other than a component, with the applicable requirements has been demonstrated by the conformity assessment procedure carried out under paragraph (b)—
 - (i) draw up an EU declaration of conformity in accordance with Regulation 15,
 - (ii) ensure that the EU declaration of conformity accompanies each product, save that where a large number of products are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy of the declaration,
 - (iii) affix a CE marking to the product in accordance with Regulation 17,
- (d) in a case where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure under paragraph (b)—
 - (i) draw up a written attestation of conformity as referred to in Regulation 14(3),
 - (ii) ensure that each component is accompanied by a copy of the attestation of conformity, save that where a large number of components are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy of the attestation,
- (e) retain 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,
- (f) ensure that procedures are in place for series production to remain in conformity with the Directive or these Regulations and that changes in a product design and characteristics and changes in the harmonised standards referred to in Regulation 13 or in other technical specifications by reference to which conformity of a product is declared, are adequately taken into account,

- (g) in a case where it is deemed appropriate by the market surveillance authority with regard to the risks presented by a product and in order to protect the health and safety of end-users—
 - (i) carry out sample testing of products made available on the market,
 - (ii) investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and
 - (iii) keep distributors informed of any such monitoring,
- (h) 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 its packaging or in a document accompanying the product,
- (i) ensure that products, other than components, which the manufacturer 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 Annex II, the text of which is set out in Schedule 2 to these Regulations,
- (j) indicate on the product in a language easily understood by end-users and the competent authorities, the manufacturer's name, registered trade name or registered trade mark and the postal address at which they can be contacted, which address shall indicate a single point of contact or, where that is not possible to do so on the product, on its packaging or in a document accompanying the product,
- (k) ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by end-users and that such instructions and safety information, as well as any labelling, are clear, understandable and intelligible,
- (l) in the case of a product which a manufacturer has placed on the market and which the manufacturer considers or has reason to believe is not in conformity with the Directive or these Regulations—
 - (i) immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it if appropriate, and
 - (ii) where the product presents a risk, immediately inform the competent authorities of the Member States in which the manufacturer made the product available on the market, giving details, in particular, of the non-compliance and of any corrective measures taken,

and

- (m) further to a reasoned request from a competent authority in respect of a product which the manufacturer has made available on the market—
 - (i) provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product with the Directive or these Regulations, in a language which can be easily understood by that authority, and
 - (ii) co-operate with that authority, at its request, on any action taken to eliminate the risks posed by products placed on the market by the manufacturer.

Authorised Representatives

8. (1) A manufacturer may, by a written mandate, appoint an authorised representative for the purposes of the Directive or these Regulations.

(2) The obligations laid down in Regulation 7(a) and the obligation to draw up technical documentation referred to in Regulation 7(b) shall not form part of the mandate of an authorised representative appointed under paragraph (1).

(3) An authorised representative appointed under paragraph (1) shall perform the tasks specified in the mandate received from the manufacturer which shall, at least, allow the authorised representative to—

- (a) keep the EU declaration of conformity or, where applicable, the attestation of conformity and the technical documentation at the disposal of competent authorities for 10 years after the product has been placed on the market,
- (b) further to a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a product, and
- (c) cooperate with a competent authority, at its request, on any action taken to eliminate the risks posed by products covered by the authorised representative's mandate.

Obligations of importers

9. (1) An importer shall not place a product on the market unless it complies with the Directive and these Regulations.

(2) An importer shall—

- (a) before placing a product on the market, ensure that—
 - (i) the appropriate conformity assessment procedure referred to in Regulation 14 has been carried out by the manufacturer,
 - (ii) the manufacturer has drawn up the technical documentation,

- (iii) the items referred to in Regulation 4(1)(a) and (b) bear the CE marking, and, are accompanied by the EU declaration of conformity and the required documents,
 - (iv) the items referred to in Regulation 4(1)(c) are accompanied by the attestation of conformity and by the required documents, and
 - (v) the manufacturer has complied with the requirements set out in Regulations 7(h), 7(i) and 7(j),
- (b) in a case where the importer considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations—
- (i) not place the product on the market until it has been brought into conformity, and
 - (ii) where the product presents a risk, inform the manufacturer and the competent authorities of the Member States to that effect,
- (c) indicate on the product, in a language which can be easily understood by end-users and competent authorities, or where it is not possible to do so on the product, in a document accompanying it, the importer's name, registered trade name or registered trade mark and the postal address at which the importer can be contacted,
- (d) ensure that the product is accompanied by instructions and safety information in a language which can be easily understood by the end-users,
- (e) ensure that, while a product is under the importer's responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II, the text of which is set out in Schedule 2 to these Regulations,
- (f) in a case where it is deemed appropriate by the market surveillance authority, with regard to the risks presented by a product and in order to protect the health and safety of end-users, the importer shall—
- (i) carry out sample testing of products made available on the market,
 - (ii) investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and
 - (iii) keep distributors informed of any such monitoring,
- (g) in a case where an importer considers or has reason to believe that a product which the importer has placed on the market is not in conformity with the Directive or these Regulations—

- (i) immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it if appropriate, and
 - (ii) where the product presents a risk, immediately inform the competent authorities of the Member States in which the importer made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken,
- (h) for 10 years after the product has been placed on the market by the importer—
- (i) keep a copy of the EU declaration of conformity or, where applicable, of the attestation of conformity at the disposal of competent authorities, and
 - (ii) ensure that the technical documentation can be made available to those authorities, upon request,
- and
- (i) further to a reasoned request from a competent authority in respect of a product which the importer has made available on the market—
- (i) 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, and
 - (ii) cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product which the importer has placed on the market.

Obligations of distributors

10. A distributor shall—

- (a) act with due care in relation to the requirements of the Directive or these Regulations when making a product available on the market,
- (b) before making a product available on the market, verify that—
 - (i) the product bears the CE marking, where applicable,
 - (ii) where applicable, that it is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents,
 - (iii) the product is accompanied by instructions and safety information, in a language which can be easily understood by the end-users in the Member State in which the product is to be made available on the market, and

- (iv) the manufacturer and the importer have complied with the requirements set out in Regulations 7(*h*), 7(*i*), 7(*j*) and 7(*k*) and Regulation 9(2)(*c*) respectively.
 - (c) in a case 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 Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations—
 - (i) not make the product available on the market until it has been brought into conformity, and
 - (ii) where the product presents a risk, inform the manufacturer or the importer to that effect as well as the competent authorities of the Member States,
 - (d) ensure that, while a product is under the distributor's responsibility, its storage or transport conditions do not jeopardise its compliance with the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations,
 - (e) in a case where the distributor considers, or has reason to believe, that a product which the distributor has made available on the market is not in conformity with the Directive or these Regulations—
 - (i) make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken, and
 - (ii) where that product presents a risk, immediately inform the competent authorities of the Member States in which the distributor made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken,
- and
- (f) further to a reasoned request from a competent authority in respect of a product which the distributor has made available on the market—
 - (i) provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the product, and
 - (ii) cooperate with that authority, at its request, on any action taken to eliminate the risks posed by the product.

Cases in which obligations of manufacturers apply to importers and distributors

11. An importer or distributor shall be considered a manufacturer for the purposes of the Directive or these Regulations, and shall be subject to the obligations of the manufacturer under Regulation 7, where that importer or distributor—

- (a) places a product on the market under the importer's or distributor's name or trademark, or
- (b) modifies a product already placed on the market in such a way that compliance with the Directive or these Regulations may be affected.

Identification of economic operators

12. An economic operator shall—

- (a) on request, identify to a competent authority any economic operator—
 - (i) who has supplied the first named economic operator with a product, or
 - (ii) to whom the first named economic operator has supplied a product, and
- (b) be able to present the information referred to in paragraph (a) for 10 years after the first named economic operator has been supplied with, or has supplied the product.

PART 3

CONFORMITY OF PRODUCTS

Presumption of conformity on the basis of harmonised standards

13. Without prejudice to the powers of the State under Article 35 and 37 of the Directive, a product which is in conformity with harmonised standards or part thereof, the references to which have been published in the Official Journal, shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations, or parts thereof.

Conformity assessment procedures

14. (1) The procedures to be followed for assessing the conformity of equipment and, where necessary the devices referred to in Regulation 4(1)(b) of these Regulations, are—

- (a) for equipment-groups I and II, equipment-categories M 1 and 1, the EU-type examination set out in Annex III to the Directive, the text of which is set out in Schedule 3 to these Regulations, in conjunction with either of the following—

- (i) conformity to type based on quality assurance of the production process set out in Annex IV to the Directive, the text of which is set out in Schedule 4 to these Regulations, or
 - (ii) conformity to type based on product verification set out in Annex V to the Directive, the text of which is set out in Schedule 5 to these Regulations,
- (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 Annex III to the Directive, the text of which is set out in Schedule 3 to these Regulations, in conjunction with either—
 - conformity to type based on internal production control plus supervised product testing set out in Annex VI to the Directive, the text of which is set out in Schedule 6 to these Regulations, or
 - conformity to type based on product quality assurance set out in Annex VII to the Directive, the text of which is set out in Schedule 7 to these Regulations,
 - (ii) in the case of other equipment in these groups and categories, internal production control set out in Annex VIII to the Directive, the text of which is set out in Schedule 8 to these Regulations and the communication of the technical documentation provided for in point 2 of that Annex and Schedule, 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 Annex VIII to the Directive, the text of which is set out in Schedule 8 to these Regulations, and
- (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 Annex IX to the Directive, the text of which is set out in Schedule 9 to these Regulations 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 and 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 Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations applicable to finished equipment or protective systems.

(4) With regard to the safety aspects referred to in paragraph 1.2.7 of Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations, in addition to the conformity assessment procedures referred to in paragraphs (1) and (2), the procedure referred to in Annex VIII to the Directive, the text of which is set out in Schedule 8 may also be followed.

(5) By derogation from paragraphs (1), (2) and (4), the market surveillance authority may, on a duly justified request in writing, authorise the placing on the market and putting into service of 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.

(6) Documents and correspondence relating to the conformity assessment procedures referred to in paragraphs (1) to (4) shall be drawn up in a language determined by the Member State concerned.

EU declaration of conformity

15. (1) An EU declaration of conformity for a product other than a component shall—

- (a) state that the fulfilment of the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations has been demonstrated,
- (b) have the model structure set out in Annex X to the Directive, the text of which is set out in Schedule 10 to these Regulations,
- (c) contain the elements specified in the relevant conformity assessment procedures set out in Annexes III to IX to the Directive, the text of which is set out in Schedules 3 to 9 to these Regulations,
- (d) be continuously updated, and
- (e) be translated into the language or languages required by the Member State in which the product is placed or made available on the market.

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

(3) 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 the Directive or these Regulations.

General principles of the CE marking

16. The CE marking when affixed to a product is subject to the general principles set out in Article 30 of Regulation (EC) No. 765/2008.

Rules and conditions for affixing the CE Marking and other markings

17. (1) Subject to paragraph (2), before the product is placed on the market, the CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate.

(2) Where it is not possible or not warranted on account of the nature of the product to affix the CE marking in accordance with paragraph (1), before the product is placed on the market, the CE marking shall be affixed to—

- (a) the packaging, and
- (b) the accompanying documents.

(3) Where a notified body is involved in the production control phase, the CE marking shall be followed by the identification number of that notified body which shall be affixed—

- (a) by the notified body itself, or
- (b) under the instructions of the notified body, by the manufacturer or his authorised representative.

(4) The CE marking and, where applicable, the identification number of the notified body shall be followed by the specific marking of explosion protection $\text{\textcircled{Ex}}$, the symbols of the equipment-group and category and, where applicable, the other markings and information referred to in paragraph 1.0.5 of Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations.

(5) The CE marking and the markings, symbols and information referred to in paragraph (4) and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use.

(6) Products that are designed for a particular explosive atmosphere shall be marked accordingly.

(7) A person shall not affix a CE marking—

- (a) in a manner that is in contravention of the Directive or these Regulations, to a product which conforms with these Regulations, or
- (b) to a product which does not conform with the Directive or these Regulations.

PART 4

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Notified bodies

18. (1) The notifying authority shall notify the European Commission and the other Member States of the conformity assessment bodies authorised under these Regulations to carry out third party conformity assessment tasks.

(2) Only conformity assessment bodies which have been notified to the European Commission and other Member States in accordance with the Directive and these Regulations and against whom no objections are raised by the European Commission or the other Member States within the time periods set down under Article 25(5) of the Directive, shall be notified bodies for the purposes of the Directive and these Regulations.

Applications for notification by conformity assessment bodies

19. (1) A conformity assessment body seeking to become a notified body shall meet the requirements set down in paragraphs 2 to 11 of Article 21 of the Directive.

(2) Without prejudice to paragraph (1), where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal, it shall be presumed to comply with the requirements set down in Article 21 of the Directive insofar as the applicable harmonised standards cover those requirements.

(3) A conformity assessment body seeking to become a notified body shall submit to the notifying authority an application, which application shall be in accordance with Article 24 of the Directive and shall be accompanied by the appropriate fee as may be prescribed by the notifying authority.

Notification of conformity assessment bodies

20. (1) The notifying authority may only notify a conformity assessment body where that body—

(a) has made an application to it in accordance with Article 24 of the Directive, and

(b) meets the requirements set out in Article 21 of the Directive.

(2) Notifications by the notifying authority under paragraph (1) shall be made in accordance with the notification procedure set down in Article 25 (2), (3) and (4) of the Directive.

(3) The notifying authority shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

(4) The assessment and monitoring referred to in Article 18(1) and (2) shall be carried out by the Irish National Accreditation Board within the meaning of and in accordance with Regulation (EC) No. 765/2008.

Changes to notifications

21. (1) Where the notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 21 of the Directive, or that it is failing to fulfil its obligations under Article 29 or 31 of the Directive or these Regulations, that authority shall restrict, suspend or withdraw notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations.

(2) In the event of restriction, suspension or withdrawal of notification, the notifying authority shall immediately inform the European Commission and the other Member States of the restriction, suspension or withdrawal of same.

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

(4) The notifying authority shall inform the notified body concerned of its decision and allow that body an opportunity to make representations to it.

(5) The notifying authority shall establish one panel per appeal (“appeal panel”) for the purposes of considering appeals under this Regulation. An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel. An appeal panel shall not consist of any person who decided or was involved in the decision to restrict, suspend or withdraw the relevant notification pertaining to a notified body. An appeal panel shall establish its own procedure.

(6) Where the notifying authority decides to restrict, suspend or withdraw notification pertaining to a notified body, the latter may, within 14 days of the notification under paragraph (4), appeal to an appeal panel against the restriction, suspension or withdrawal, as the case may be. The notification pertaining to a notified body stands restricted, suspended or withdrawn, as the case may be, from the date of the notification of the decision under paragraph (4), unless the appeal panel, upon an application to it, decides otherwise, pending the outcome of the appeal. On hearing the appeal the appeal panel may confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision. The decision of the appeal panel is final except that an appeal lies to the High Court on application to it on a specified point of law. Such an application does not affect the decision of the appeal panel and its operation.

(7) All expenses reasonably incurred by the notifying authority in relation to an appeal before an appeal panel or the High Court shall be borne by the appellant where the appeal panel or the court confirms or confirms with a variation the decisions of the notifying authority. The notifying authority may

recover these expenses as a simple contract debt in a court of competent jurisdiction.

Subsidiaries of and subcontracting by notified bodies

22. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall comply with Article 23 of the Directive.

Operational obligations of notified bodies

23. (1) Subject to paragraph (2), a notified body shall—

- (a) carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes III to VII and Annex IX to the Directive, the text of which is set out in Schedules 3 to 7 and Schedule 9 of these Regulations,
- (b) ensure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for economic operators,
- (c) perform its 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,
- (d) in a case where it finds that the essential health and safety requirements set out in Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations, or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, require that manufacturer to take appropriate corrective measures and shall not issue a certificate of conformity,
- (e) in a case where, in the course of the monitoring of conformity following the issue of a certificate, the notified body finds that a product no longer complies, require the manufacturer to take appropriate corrective measures and suspend or withdraw the certificate if necessary,
- (f) in a case where corrective measures under paragraph (e) are not taken by the manufacturer or do not have the required effect, restrict, suspend or withdraw any certificates, as appropriate,
- (g) inform the manufacturer in question where a decision to restrict, suspend or withdraw any certificate is taken under paragraph (f), and
- (h) participate in the sectoral group of notified bodies established in accordance with Article 33 of the Directive.

(2) In carrying out its functions under paragraph 1(b) and 1(c) of this Regulation, a notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the Directive or these Regulations.

Appeal against decisions of notified bodies

24. (1) The notifying authority shall establish one panel per appeal (“appeal panel”) for the purposes of considering appeals against restrictions, suspensions or withdrawals rendered by notified bodies under Regulation.

(2) An appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel. An appeal panel shall not consist of any person who decided or was involved in the decision to restrict, suspend or withdraw the relevant certificate. An appeal panel shall establish its own procedure.

(3) Where a notified body decides to restrict, suspend or withdraw a certificate held by a manufacturer, the latter may, within 14 days of the notification of a decision under Regulation 23(g) appeal to an appeal panel against the restriction, suspension or withdrawal, as the case may be. The certification held by the manufacturer stands restricted, suspended or withdrawn, as the case may be, from the date of notification of the decision under Regulation 23(g), unless the appeal panel, upon an application to it, decides otherwise, pending the outcome of the appeal. On hearing the appeal the appeal panel may confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision. The decision of the appeal panel is final except that an appeal lies to the High Court on application to it on a specified point of law. Such an application does not affect the decision of the appeal panel and its operation.

Information obligation on notified bodies

25. A notified body shall—

- (a) inform the notifying authority of the matters referred to in Article 31(a), (b), (c) and (d) of the Directive,
- (b) provide other bodies notified under the Directive or these Regulations carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative conformity assessment results,
- (c) on request, provide other bodies notified under the Directive or these Regulations carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to positive conformity assessment results.

PART 5

MARKET SURVEILLANCE, SAFEGUARD PROCEDURE

Market surveillance

26. The market surveillance authority shall organise and carry out market surveillance of products covered by these Regulations in accordance with Articles 16 to 29 of Regulation (EC) No. 765 of 2008.

Procedure for dealing with products presenting a risk at national level

27. (1) Where the market surveillance authority has sufficient reason to believe that a product covered by these Regulations presents a risk to the health or safety of persons or to domestic animals or property, it shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in the Directive or these Regulations.

(2) The relevant economic operator shall cooperate with the market surveillance authority as deemed necessary by it in carrying out an evaluation under paragraph (1).

(3) Where, in the course of the evaluation referred to in paragraph (1), the market surveillance authority finds that the product does not comply with the requirements laid down in the Directive or these Regulations, it shall—

- (a) without delay require the relevant economic operator to take all appropriate corrective actions to bring the product into compliance with those requirements, to withdraw the product from the market, or to recall it within a reasonable period commensurate with the nature of the risk, as the authority prescribes,
- (b) inform the notified body who carried out the conformity assessment procedure on the product of the product's non-compliance, and
- (c) apply the provisions of Article 21 of Regulation (EC) No 765/2008 to the measures referred to in paragraph 3(a) of this Regulation.

(4) Where the market surveillance authority considers that non-compliance is not restricted to the State, it shall inform the European Commission and the other Member States of the results of the evaluation and of the actions which it has required the economic operator to take.

(5) The relevant economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned that it has made available on the market throughout the European Economic Area.

(6) Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph (3)(a) of this Regulation, the market surveillance authority shall, without delay, take all appropriate provisional measures to prohibit or restrict the product from being made available on the market in the State, to withdraw the product from that market or to recall it.

(7) The market surveillance authority shall inform the European Commission and the other Member States, without delay, of any measures taken under paragraph (6), and shall—

- (a) include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the

nature and duration of the measures taken in the State and the arguments put forward by the relevant economic operator, and

(b) in particular, indicate whether the non-compliance is due to either—

(i) the failure of the product to meet requirements relating to the health or safety of persons or, to the protection of domestic animals or property, or

(ii) shortcomings in the harmonised standards referred to in Regulation 13 conferring a presumption of conformity.

(8) Where another Member State has initiated the procedure under Article 35 of the Directive, the market surveillance authority shall, without delay, inform the European Commission and the other Member States—

(a) of any measures adopted and of any additional information at its disposal relating to the non-compliance of the product concerned, or

(b) of its objections, in the event of disagreement with the adopted measure of the other Member State.

(9) Where, within three months of receipt of the information referred to in paragraph (7), no objection has been raised by either a Member State or the European Commission in respect of a provisional measure taken by the market surveillance authority, that measure shall be deemed to be justified.

(10) The market surveillance authority shall ensure that appropriate restrictive measures, such as withdrawal of the product from the market, are taken in respect of the product concerned without delay.

Safeguard procedure

28. (1) Where a national measure taken by a Member State under Article 35 of the Directive is considered justified by the European Commission in accordance with the procedure in Article 36(1) of the Directive, the market surveillance authority shall take the necessary measures to ensure that the non-compliant product is withdrawn from the market in the State and shall inform the European Commission accordingly.

(2) Where a national measure taken by a Member State under Article 35 of the Directive is considered unjustified by the European Commission in accordance with the procedure in Article 36(1) of the Directive, the market surveillance authority shall withdraw that measure.

Compliant products which present a risk


29. (1) Where, having carried out an evaluation under Regulation 27, the market surveillance authority finds that although a product is in compliance with the Directive or these Regulations, it presents a risk to the health or safety of persons or to domestic animals or to property, it shall—

- (a) require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe and,
- (b) immediately inform the European Commission and the other Member States, of all available details and in particular of—
 - (i) the data necessary for the identification of the product concerned,
 - (ii) the origin and the supply chain of the product,
 - (iii) the nature of the risk involved, and
 - (iv) the nature and the duration of the national measures taken.

(2) An economic operator shall ensure that the corrective action required under paragraph (1) is taken in respect of all products concerned that the operator has placed or made available on the market throughout the European Economic Area.

Formal non-compliance

30. (1) Without prejudice to Regulation 27, the market surveillance authority shall require the relevant economic operator to put an end to the non-compliance concerned where it finds that—

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 16 of the Directive or Regulation 17 of these Regulations,
- (b) the CE marking, when 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 Annex II to the Directive, the text of which is set out in Schedule 2 of these Regulations 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 Article 16 of the Directive or Regulation 17 of these Regulations, 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) the technical documentation is either not available or not complete,

- (h) the information referred to in Articles 6(7) or 8(3) of the Directive or Regulation 7(j) or Regulation 9(2)(c) of these Regulations is absent, false or incomplete, or
- (i) any other administrative requirement provided for in Articles 6 or 8 of the Directive or Regulation 7 or Regulation 9 of these Regulations is not fulfilled.

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

PART 6

POWERS OF THE MARKET SURVEILLANCE AUTHORITY

General

31. (1) The market surveillance authority shall perform its market surveillance duties in accordance with the relevant provisions of Article 34 of the Directive.

(2) 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 the Directive and these Regulations.

(3) 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.

Powers of inspectors

32. (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—
 - (i) the premises of an economic operator, or
 - (ii) any other place or premises where entry on same is necessary to ensure that the objectives of the Directive are achieved;
- (b) inquire into, search, examine and inspect—
 - (i) any place referred to in paragraph 1(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 the Directive or 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 the Directive or 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 the Directive or 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 the Directive or 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 the Directive or 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, save that the person in charge is responsible for his or her own costs in attending at the exercise of the inspector's powers and cannot unreasonably delay the inspector in the exercise of those powers;

- (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 the Directive or 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 recall or removal from the market of a product by the person who has placed or made available that product on the market, where it appears to the inspector that, in relation to that product, the Directive or 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 market surveillance 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 or premises specified in Regulation 32(1)(a), 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 premises any records (including documents stored in a non-legible form) or information, relating to a place, premises or to a product, that the inspector requires to inspect for the purposes of the Directive or these Regulations, held at any place or premises, or

(b) there is, or such an inspection is likely to disclose, evidence of a contravention of the Directive or 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 that place or premises, 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 market surveillance 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 paragraph (1)(i), (k) or (l) shall not be admissible in proceedings brought against that person for an offence (other than an offence under Regulation 42(4)) relating to a breach of, or failure to comply with, an obligation in the said paragraph (1)(i), (k) or (l).

Measures entailing refusal or restriction

33. An inspector who finds that—

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No. 765/2008, Article 16 of the Directive or of Regulation 17 of these Regulations,
- (b) the CE marking, where required, has not been affixed,
- (c) the specific marking of explosion protection Ex , 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 Annex II to the Directive, the text of which is set out in Schedule 2 to these Regulations, 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 Article 16 of the Directive and Regulation 17 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 Articles 6(7) or 8(3) of the Directive or Regulation 7(j) or 9(2)(c) is absent, false or incomplete, or
- (i) any other administrative requirement provided for in Articles 6 or 8 of the Directive or Regulation 7 or 9 is not fulfilled,

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

Contravention notice

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

- (a) is contravening or has contravened any of the provisions of the Directive or these Regulations, or
- (b) has failed to comply with a direction under Regulation 33,

may serve a 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) cease placing or making available the product on the market or putting it into use,
 - (iii) remove the product from the market,
 - (iv) recall the product,
 - (v) dispose of the product,
 - (vi) destroy the product where it presents a serious risk,

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 Regulation 35(1),
- (e) include information regarding the making of an appeal under Regulations 35(1) and 35(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 35(1) extend the period specified under paragraph (2) (d) of this Regulation.

(7) Where there is no appeal under Regulation 35(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

35. (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 market surveillance 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 34(1) shall have the opportunity to make representations within 10 working days of first being advised of the inspector's intention, to the market surveillance authority in advance of the measure being taken.

(5) Where, due to the urgency of the measure referred to in Regulation 34(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 market surveillance authority shall give such opportunity, as soon as may be, thereafter.

Prohibition notice

36. (1) A prohibition notice may be served by an inspector—

- (a) on the person who is or who may reasonably be presumed to be in control of the activity concerned, where that inspector is of the opinion that at any place there is occurring or is likely to occur any activity relating to a product that gives rise to or is likely to give rise to a serious risk requiring rapid intervention, including a serious risk the effects of which are not immediate, or
- (b) on any person in relation to a product in respect of which a direction under Regulation 33 or a contravention notice has been issued but not complied with.

(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 Directive or 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 37(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 gives rise to 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

37. (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 36(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 this Regulation,

shall at the same time notify the market surveillance authority of the appeal or the application, and the grounds for the appeal or application.

(4) In the case of an appeal or any application to suspend the operation of the prohibition notice under this Regulation, the market surveillance authority shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or application.

(5) 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

38. (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.

Information notice

39. (1) An inspector or the market surveillance authority may, by notice served on a person, require the person to give, within such period and in such form as may be specified in the notice, any information specified in the notice that the inspector or the authority may reasonably require for the proper performance by it of his or her or its functions under the Directive or these Regulations.

(2) Upon the written application of the person on whom the notice is served, the period specified in the information notice may be extended by and at the discretion of—

- (i) the market surveillance authority, or
- (ii) an inspector.

(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) A person who appeals under paragraph (3) shall at the same time notify the market surveillance 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.

(5) 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.

(6) Subject to paragraph (7), 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.

(7) 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 (5), the end of the period of suspension,

whichever occurs latest.

Service of notifications

40. (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,

(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, or

(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

41. (1) The market surveillance authority may provide information to any European Union information network, the European Commission or a competent authority of another Member State for the purpose of sharing information related to the application of the Directive.

(2) The market surveillance 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 7

OFFENCES AND PENALTIES

Offences

42. (1) A person who contravenes a provision or requirement of Regulation 5, 7, 8(3), 9, 10, 12, 27(2), 27(5) or 29(2) commits an offence.

(2) A person who contravenes a requirement of Regulation 32, 33, 34, 36 or 39, or a notice issued or measure taken thereunder 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 uses a marking or document so forged or counterfeited, or which is false as aforesaid,
- (d) knowingly 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, 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 32(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 40(1)(e), removes, alters, damages or defaces the notice without lawful authority commits an offence.

(7) A person who, prevents or attempts to prevent any person from answering any question to which an inspector may require an answer under Regulation 32, commits an offence.

(8) A person who, fails to comply with a bona fide request, instruction or directions from an inspector in the exercise of his or her functions under these Regulations, commits an offence.

(9) Where an offence under any of these Regulations is committed by reason of a failure to do something at or within a time fixed by or under any of those provisions, the offence shall be deemed to continue until that thing is done.

(10) A person who states to the market surveillance 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.

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

Penalties

43. (1) A person guilty of an offence under Regulation 42 shall be liable—

(a) on summary conviction, to a class A fine 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 market surveillance 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

44. 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

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

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under Regulation 42 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 8

MISCELLANEOUS

Appeal to Circuit Court from certain orders of District Court

46. For the avoidance of doubt, an order of the District Court confirming, varying or cancelling a notice under Regulation 34, 36 or 39 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

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

Immunity

48. None of the following persons, that is to say, the market surveillance authority, an inspector, or a member or a member of staff of the market surveillance authority shall be liable in damages in respect of any act done or omitted to be done by it or him or her in the performance, or purported performance, of that person's functions under these Regulations, unless the act or omission concerned was done in bad faith.

Indemnification

49. The market surveillance authority shall, subject to the provisions of any enactment or rule of law, indemnify an inspector appointed by it, or a member or a member of staff of the market surveillance authority, in respect of any act done or omitted to be done by him or her in the performance, or purported performance, of his or her functions under these Regulations as such inspector, member or member of staff, unless the act or omission concerned was done in bad faith.

Restrictions on the disclosure of information

50. A person in receipt of information as a result of the application of these Regulations shall treat same as confidential. In particular, business, professional and trade secrets shall be treated as confidential unless the divulging of such information is—

- (a) for the purpose of the discharge of functions under these Regulations,
- (b) made with the consent of the person to whom the information applies, or
- (c) for the purposes of—
 - (i) any legal proceedings (including by means of a report to a coroner holding an inquest under the Coroners Acts 1962 and 2005 on the body of a person whose death may have been caused through personal injury), or
 - (ii) any investigation or special report under section 70 of the Act of 2005,

- (d) necessary in order to protect the health and safety of persons,
- (e) required by the provisions of these Regulations or the Directive, or
- (f) ordered by a court of law.

Transitional

51. (1) The making available on the market of products or the putting into service of a product, in conformity with Directive 94/9/EC or the Regulations of 1999, and which was placed on the market or put into service before 20 April 2016 continues to be lawful.

(2) Certificates issued under Directive 94/9/EC or the Regulations of 1999 continue to be valid under these Regulations.

Revocation

52. The European Communities (Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres) Regulations, (S.I. No. 83 of 1999) are revoked.

SCHEDULE 1**TEXT OF 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 Schedule 2.

- (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 Schedule 2.

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 Schedule 2.

- (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.

The means of protection relating to equipment in this category ensure the requisite level of protection, even in the event of frequently occurring disturbances or equipment faults which normally have to be taken into account.

Equipment in this category must comply with the supplementary requirements referred to in point 2.2 of Schedule 2.

- (c) Equipment category 3 comprises equipment designed to be capable of functioning in conformity with the operating parameters established by the manufacturer and ensuring a normal 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 unlikely to occur or, if they do occur, are likely to do so only infrequently and for a short period only.

Equipment in this category ensures the requisite level of protection during normal operation.

Equipment in this category must comply with the supplementary requirements referred to in point 2.3 of Schedule 2.

Regulations 6, 7, 9, 10, 13, 14, 15, 16, 23, 30 and 33

SCHEDULE 2

TEXT OF 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/or to limit the range of explosion flames and explosion pressures to a sufficient level of safety.

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, registered trade name or registered trade mark, and address of the manufacturer,
- CE marking, (see Annex II to Regulation (EC) No 765/2008),
- designation of series or type,
- batch or 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),

or

- 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 batch or serial number (see point 1.0.5), together with any appropriate additional information to facilitate maintenance (e.g. address of the repairer, etc.);

- 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, mechanical 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 releases of 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 or 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 point are wholly or partly covered by other Union legislation 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 that specific Union legislation.

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/or similar types of monitoring devices.

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, electromagnetic 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 and/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.

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/or 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/or ignition limits 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 mists.

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 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.

2.1.2.2. 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 positioned 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 possible 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.

SCHEDULE 3**TEXT OF 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 the 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 the 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 the 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 the 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 the 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 apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may

no longer comply with the applicable requirements of the 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 the 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**TEXT OF 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 the Directive that apply to them.

2. Manufacturing

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:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to equipment quality;
 - (b) the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;
 - (c) the examinations and tests which will be carried out before, during and after manufacture and the frequency with which they will be carried out;
 - (d) the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.;
 - (e) 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 the 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 the 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 the 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**TEXT OF 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 the 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 the 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 the 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 the 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 the 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**TEXT OF 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 the 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 the 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 the 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 the 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**TEXT OF 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 the Directive that apply to them.

2. Manufacturing

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 the 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:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
 - (b) the examinations and tests that will be carried out after manufacture;
 - (c) the quality records, such as inspection reports and test data, calibration data, reports on the personnel concerned, etc.
 - (d) 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 the 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 the 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:
 - (a) 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 the 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**TEXT OF 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 the 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 the 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 the 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 the 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 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 9**TEXT OF 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 the 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 the 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 the 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 the 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 the 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 manufacturer's 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

TEXT OF ANNEX X TO THE DIRECTIVE

EU DECLARATION OF CONFORMITY (No XXXX)⁶

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):

⁶It is optional for the manufacturer to assign a number to the declaration of conformity.

Regulation 2

SCHEDULE 11**TEXT OF ANNEX XII TO THE DIRECTIVE****CORRELATION TABLE**

Directive 94/9/EC	Directive 2014/33/EU
Article 1(1)	Article 1(1)(a)
Article 1(2)	Article 1(1)(b)
—	Article 1(1)(c)
Article 1(3)	Article 2(1) to (9)
—	Article 2(10) to (26)
Article 1(4)	Article 1(2)
Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
Article 5(1), first subparagraph	—
Article 5(1), second subparagraph	Article 12(2)
Article 5(2)	Article 12(1)
Article 5(3)	—
—	Articles 6 to 11
—	—
Article 6(1) and (2)	—
Article 6(3)	Article 39(1) to (4)
—	Article 39(5), first subparagraph
Article 6(4)	Article 39(5), second subparagraph
Article 7	—
Article 8(1) to (6)	Article 13(1) to (6)
Article 8(7)	—
—	Articles 14 and 15
Article 9	—
Article 10(1)	—
Article 10(2)	Article 16(1)
Article 10(3)	—
—	Article 16(2) to (6)
—	Articles 17 to 33
Article 11	—
—	Articles 34 to 38
Articles 12 and 13	—
—	Article 40
—	Article 41(1)
Article 14(1)	—

Directive 94/9/EC	Directive 2014/33/EU
Article 14(2)	Article 41(2)
Article 14(3)	—
Article 15(1)	Article 42(1)
Article 15(2)	—
—	Article 42(2)
—	Articles 43 and 44
Article 16	Article 45
Annexes I to IX	Annexes I to IX
Annex X	—
Annex XI	—
—	Annex X
—	Annex XI
—	Annex XII



GIVEN under my Official Seal,
26 May 2017.

MARY MITCHELL O'CONNOR,
Minister for Jobs, Enterprise and Innovation.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations transpose into national legislation the provisions of Directive 2014/34/EU which set out the requirements for the making available on the market and putting into service, as well as the essential health and safety requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres, (known as ATEX). These Regulations also set out the obligations on economic operators in relation to these products and the required conformity assessment procedures for such ATEX products. These Regulations also give further effective to Regulation (EC) No. 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No. 339/93 and include duties to have proper market surveillance procedures consistent with EU Regulation 765/2008.

These Regulations do not impede the making available on the market of products covered by Directive 94/9/EC which are in conformity with that Directive and which were placed on the market before 20 April 2016.

The Regulations revoke and replace the European Communities (Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres) Regulations 1999, (S.I. No. 83 of 1999).

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