

L.N. 372 of 2002

**PRODUCT SAFETY ACT
(ACT NO. V OF 2001)**

**Equipment and Protective Systems intended for use in Potentially
Explosive Atmospheres Regulations, 2002**

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

1.1 The title of these regulations is the Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres Regulations, 2002. Citation and
Commencement

1.2 These regulations shall become operative on such date as notified by the Authority in the Gazette.

1.2.1 Provided that EC certificates of conformity to the harmonised standards obtained in accordance with the procedures laid down in Directives 76/117/EEC¹, 79/196/EEC² and 82/130/EEC³, to be repealed as from 1st July 2003, shall continue to be valid until 30th June 2003 unless they expire before that date. Their validity shall continue to be limited to the harmonised standards indicated in the aforementioned Directives.

2.1 These regulations shall apply to equipment and protective systems intended for use in potentially explosive atmospheres. Scope

2.1.1 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 are also covered by the scope of these regulations.

¹OJ No. L24, 51-01-76, P.45.

²OJ No. L 43, 20-02-79, P.20, as amended by Commission directives 84/47/EEC, 88/571/EEC, 94/26/EC and 97/53/EC

³OJ No. L59, 02-03-82, P.10, as amended by Commission directives 88/35/EEC, 91/269/EC, 94/44/EC and 98/65/EC.

Definitions.

3.1 For the purposes of these regulations, the following definitions shall apply:

3.1.1 Equipment and protective systems intended for use in potentially explosive atmospheres.

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

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

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

3.1.2 Explosive atmospheres.

3.1.2.1 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.

3.1.3 Potentially explosive atmosphere.

3.1.3.1 An atmosphere which could become explosive due to local and operational conditions.

3.1.4 Equipment groups and categories.

3.1.4.1 Equipment group I applies to equipment intended for use in underground parts of mines, and to those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust.

3.1.4.2 Equipment group II applies to equipment intended for use in other places liable to be endangered by explosive atmospheres.

3.1.4.3 The categories of equipment defining the required levels of protection are described in Annex I of the Directive, which is set out in Schedule I to these regulations.

3.1.4.4 Equipment and protective systems may be designed for a particular explosive atmosphere. In this case, they must be marked accordingly.

3.1.5 Intended use.

3.1.5.1 The use of equipment, protective systems, and devices referred to in regulation 2.1.1 in accordance with the equipment group and category and with all the information supplied by the manufacturer which is required for the safe functioning of equipment, protective systems and devices.

3.1.6 The following are excluded from the scope of these regulations:

- medical devices intended for use in a medical environment,
- equipment and protective systems where the explosion hazard results exclusively from the presence of explosive substances or unstable chemical substances,
- 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,
- personal protective equipment covered by Mandatory Order M34 of 1998⁴,
- seagoing vessels and mobile offshore units together with equipment on board such vessels or units,
- means of transport, which are vehicles and their trailers intended solely for transporting passengers by air or by road, rail or water networks, as well as means of transport in so far as such means are designed for transporting goods by air, by public road

⁴ L. N. 122 of 1998.

or rail networks or by water. Vehicles intended for use in a potentially explosive atmosphere shall not be excluded,

- the equipment covered by Article 296 of the EC Treaty, that is equipment connected with the production of or trade in arms munitions and war material.

3.1.7 “the Directive” means Council Directive 94/9/EC⁵ on the approximation of the laws of the Member States concerning equipment and protective systems intended for use in potentially explosive atmospheres.

3.1.8 “notified body” means a body, notified to the Commission and to the Member States of the Community, assessed according to the criteria laid down in Annex XI of the Directive, which is set out in Schedule XI to these regulations and appointed to carry out the procedures referred to in regulations 8.1 to 8.6 of these regulations and Article 8 of the Directive. The names of such bodies are published in the *Official Journal of the European Communities*.

3.1.9 “Harmonised Standard” means a technical specification adopted by the European Committee for Standardisation (CEN) or the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), upon a remit from the European Commission in accordance with Directive 98/34/EC⁶ of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical standards and Regulations as amended by Directive 98/48/EC⁷ of the European Parliament and of the Council.

3.1.10 “National Standard transposing the Harmonised Standard” means a Standard issued by one of the members of CEN/CENELEC/ETSI which is declared and noted to be identical to the Harmonised Standard originally issued by CEN/CENELEC/ETSI.

3.1.11 “OJ” means the Official Journal of the European Communities.

3.1.12 “Community” means the European Community.

3.1.13 “CE marking” means marking as set out in Annex X of the Directive, which is set out in Schedule X to these regulations.

⁵ OJ No. L100, 19-04-94, P.1.

⁶ OJ No. L204, 21-07-98, P.37.

⁷ OJ No. L217, 05-08-98, P.18.

3.1.14 “placing on the market” means the initial action of making a product available for the first time on the Community or Maltese market, with a view to distribution or use in the Community or Malta.

3.1.14.1 Making available can be either for payment or free of charge.

3.1.14.2 Putting into service takes place at the moment of first use within the Community or Malta by the end user.

3.1.15 “manufacturer” means the person, who is primarily responsible for designing and manufacturing the equipment, protective systems, and devices so that these comply with the requirements of these regulations.

3.1.16. “authorized representative” means any person (or organisation) established in the Community or Malta who has been appointed by the manufacturer to act on his behalf in carrying out certain tasks required by these regulations.

3.1.17 “importer” means any person who places the equipment, protective systems, and devices from a foreign country on to the Community or Maltese market so that he supplies such equipment, protective systems, and devices on the first occasion that they are supplied in the Community or Malta.

3.1.18 “person who supplies equipment, protective systems, and devices” means a wholesaler, distributor, retailer or such other person.

3.1.19 “responsible person” in relation to equipment and protective systems intended for use in potentially explosive atmospheres means:

- (a) the manufacturer thereof;
- (b) the manufacturer’s authorized representative; or
- (c) where the manufacturer is not established in the Community or Malta and he has not appointed an authorized representative, the person who places this equipment on the Community or Maltese market.

4.1 The provisions of these regulations are applicable to all imported equipment and protective systems intended for use in potentially explosive atmospheres, as well as to those manufactured for the local market. Applicability

4.1.1 Regulation 4.1 above shall not be construed to prohibit any person from possessing for supply at any time before it is supplied, offered for supply or exposed for supply in Malta for the first time, or before it is agreed for the first time to supply it in Malta, any equipment referred to in regulations 2.1 and 2.1.1 of these regulations which has been manufactured or imported into Malta and which does not comply with the requirements of these regulations.

4.2 The provisions of these regulations shall apply without prejudice to any other regulations or legislation concerning the safety and protection of persons and, in particular, workers using the equipment, protective systems, or devices referred to in regulation 2.1.1 of these regulations, provided that such equipment, protective systems, or devices are not modified in a way not specified in these regulations.

4.3 Subject to regulation 4.4 below, the provisions of these regulations shall not apply to equipment and protective systems intended for use in potentially explosive atmospheres made exclusively for export.

4.4 Subject to regulations 9.1 to 9.4.2 below, regulation 4.3 above shall not apply if the CE marking or any inscription liable to be confused therewith is affixed to the equipment and protective systems intended for use in potentially explosive atmospheres.

Conformity.

5.1 All appropriate measures shall be taken to ensure that the equipment, protective systems and devices referred to in regulations 2.1 and 2.1.1 to which these regulations apply may be placed on the market and put into service only if, when properly installed and maintained and used for their intended purpose, they do not endanger the health and safety of persons and, where appropriate, domestic animals or property.

5.2 At trade fairs, exhibitions, demonstrations, etc., the showing of equipment, protective systems, or the devices referred to in regulations 2.1 and 2.1.1 which do not conform to the provisions of these regulations shall not be prevented, provided that a visible sign clearly indicates that such equipment, protective systems, and devices referred to in regulations 2.1 and 2.1.1 do not conform and that they are not for sale until they have been brought into conformity by the responsible person. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

5.3 Equipment, protective systems, and the devices referred to in regulations 2.1 and 2.1.1 to which these regulations applies must meet the essential health and safety requirements set out in Annex II of the Directive, which is set out in Schedule II to these regulations which apply to them, account being taken of their intended use.

5.4 The placing on the market and the putting into service of equipment, protective systems, or devices referred to in regulations 2.1 and 2.1.1 which comply with these regulations, shall not be prohibited, restricted or impeded.

5.5 The placing on the market of components which, accompanied by a certificate of conformity as referred to in regulation 8.3 of these regulations, are intended to be incorporated into equipment or protective systems within the meaning of these regulations shall not be prohibited, restricted or impeded.

6.1. Equipment, protective systems, and devices referred to in regulations 2.1 and 2.1.1 of these regulations, when accompanied by the EC declaration of conformity referred to in Annex III of the Directive, which is set out in Schedule III to these regulations and bearing the CE marking provided for in regulations 9.1 to 9.4.2 of these regulations, shall be regarded as conforming to all the provisions of these regulations, including the relevant conformity assessment procedures laid down in regulations 8.1 to 8.6 of these regulations and Article 9 of the Directive.

CE marking and
certificates of
conformity.

6.2 The components referred to in regulation 5.5, accompanied by the certificate of conformity referred to in regulation 8.3 to these regulations shall be regarded as conforming to all the provisions of these regulations, including the relevant conformity assessment procedures laid down in regulations 8.1 to 8.6 of these regulations and Article 9 of the Directive.

6.2.1 In the absence of harmonised standards, any steps deemed necessary shall be taken to bring to the attention of the parties concerned the existing national technical standards and specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements referred to in Annex II of the Directive, which is set out in Schedule II to these regulations.

6.3 Where a national standard transposing a harmonised standard, the reference for which has been published in the *Official Journal of the European Communities*, covers one or more of the essential health and safety requirements, the equipment, protective systems and devices referred to in regulations 2.1 and 2.1.1 of these regulations, or the components referred to in regulation 5.5 of these regulations, when constructed in accordance with that standard, shall be presumed to comply with the relevant essential health and safety requirements.

6.4 Where the equipment, protective systems and devices referred to in regulation 2.1.1 of these regulations are subject to other Community Directives covering other aspects which also provide for the affixing of the CE marking referred to in regulations 9.1 to 9.4.2 of these regulations, that marking shall indicate that the equipment, protective systems and

devices referred to in regulation 2.1.1 of these regulations are also presumed to conform with the provisions of those other Directives.

6.4.1 However, where one or more of those Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only with the Directives applied by the manufacturer. In this case, particulars of the said Directives, as published in the *Official Journal of the European Communities*, must be given in the documents, notices or instructions required by the Directives and accompanying the equipment, protective systems and devices referred to in regulation 2.1.1 of these regulations.

Withdrawal and
prohibition from
market.

7.1 Where it is ascertained that equipment, protective systems or devices referred to in regulations 2.1 and 2.1.1 of these regulations, when bearing the CE conformity marking and used in accordance with their intended use are liable to endanger the safety of persons and, where appropriate, domestic animals or property, all appropriate measures shall be taken to withdraw such equipment or protective systems from the market, to prohibit the placing on the market, putting into service or use thereof, or to restrict free movement thereof.

7.2 Where equipment, a protective system or a device referred to in regulation 2.1.1 of these regulations which does not comply bears the CE conformity marking, all appropriate action shall be taken against the person(s) having affixed the marking or against the responsible person.

7.3 The Consumer and Industrial Goods Directorate⁵ of the Malta Standards Authority shall be immediately informed of any such measures taken under regulations 7.1 and 7.2 above, indicating the reasons for such decision and, in particular, whether non-conformity is due to:

- (a) failure to satisfy the essential requirements referred to in regulation 5.3 of these regulations;
- (b) incorrect application of the standards referred to in regulation 6.3 of these regulations;
- (c) shortcomings in the standards referred to in regulation 6.3 of these regulations.

7.4 The Consumer and Industrial Goods Directorate of the Malta Standards Authority shall immediately inform the Commission of any measures taken in pursuance of regulations 7.1 and 7.2 of these regulations.

⁵L.N. 213 of 2000 - Malta Standards Authority (Establishment of Directorates) Order, 2000, published in the Government Gazette No. 17,002 of 20th October, 2000.

8.1 The procedures for assessing the conformity of equipment, including where necessary the devices referred to in regulation 2.1.1, shall be as follows:

8.1.1 *Equipment-group I and II, equipment-category M 1 and 1*

8.1.1.1 The manufacturer or his authorized representative must, in order to affix the CE marking, follow the EC type-examination procedure (referred to in Annex III of the Directive, which is set out in Schedule III these regulations), in conjunction with:

- the procedure relating to production quality assurance (referred to in Annex IV of the Directive, which is set out in Schedule IV to these regulations),
- or
- the procedure relating to product verification (referred to in Annex V of the Directive, which is set out in Schedule V to these regulations);

8.1.2 *Equipment-group I and II, equipment-category M 2 and 2*

8.1.2.1 In the case of internal combustion engines and electrical equipment in these groups and categories, the manufacturer or his authorized representative shall, in order to affix the CE marking, follow the EC-type examination procedure (referred to in Annex III of the Directive, which is set out in Schedule III to these regulations), in conjunction with:

- the procedure relating to conformity to type referred to in Annex VI of the Directive, which is set out in Schedule VI to these regulations,
- or
- the procedure relating to product quality assurance referred to in Annex VII of the Directive, which is set out in Schedule VII to these regulations;

8.1.2.2 In the case of other equipment in these groups and categories, the manufacturer or his authorized representative must, in order to affix the CE marking, follow the procedure relating to internal control of production (referred to in Annex VIII of the Directive, which is set out in Schedule VIII to these regulations) and communicate the dossier provided for in Annex VIII, paragraph 3 of the Directive, which is set out in Schedule VIII to these regulations, to a notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

8.1.3 *Equipment-group II, equipment-category 3*

8.1.3.1 The manufacturer or his authorized representative must, in order to affix the CE marking, follow the procedure relating to internal control of production referred to in Annex VIII of the Directive, which is set out in Schedule VIII to these regulations;

8.1.4 *Equipment-groups I and II*

8.1.4.1 In addition to the procedures referred to in regulations 8.1.1, 8.1.2 and 8.1.3, the manufacturer or his authorized representative may also, in order to affix the CE marking, follow the procedure relating to CE unit verification (referred to in Annex IX of the Directive, which is set out in Schedule IX to these regulations).

8.2 The provisions of regulations 8.1.1 or 8.1.4 above shall be used for conformity assessment of autonomous protective systems.

8.3 The procedures referred to in regulation 8.1 of these regulations shall be applied in respect of components as referred to in regulation 5.5 of these regulations, with the exception of the affixing of the CE marking. A written attestation shall be issued by the manufacturer or his authorized representative, declaring the conformity of the components with the provisions of these regulations which apply to them and stating their characteristics and how they must be incorporated into equipment or protective systems to assist compliance with the essential requirements applicable to finished equipment or protective systems.

8.4 In addition, the manufacturer or his authorized representative may, in order to affix the CE marking, follow the procedure relating to internal control of production (referred to in Annex VIII of the Directive, which is set out in Schedule VIII to these regulations) with regard to the safety aspects referred to in item 1.2.7 of Annex II of the Directive, which is set out in Schedule II to these regulations.

8.5 Notwithstanding the previous regulations, the placing on the market and putting into service of the equipment, protective systems and individual devices referred to in regulation 2.1.1, in respect of which the procedures referred to in the previous regulations have not been applied, and the use of which is in the interests of protection, may be authorized on duly justified request.

8.6 Documents and correspondence relating to the procedures referred to in the abovementioned regulations shall be drawn up in Maltese or in any other Community language accepted by the notified body.

9.1 The CE conformity marking shall consist of the initials "CE" in the form shown in the specimen in Schedule X to these regulations. The CE marking shall be followed by the identification number of the notified body where such body is involved in the production control stage.

CE Conformity
Marking

9.2 The CE marking shall be affixed distinctly, visibly, legibly and indelibly to equipment, protective systems and devices referred to in regulation 2.1.1 of these regulations, supplementary to the provisions of point 1.0.5 of Annex II of the Directive, which is set out in Schedule II to these regulations.

9.3 The affixing of markings on the equipment, protective systems or devices referred to in regulation 2.1.1 of these regulations which are likely to deceive third parties as to the meaning and form of the CE marking shall be prohibited. Any other marking may be affixed to the equipment, protective systems or devices referred to in regulation 2.1.1 of these regulations provided that the visibility and legibility of the CE marking is not thereby reduced.

9.4. Without prejudice to regulations 7.1 and 7.2 of these regulations:

9.4.1 where it is established that the CE marking has been incorrectly affixed, the responsible person shall be obliged to bring the product into conformity as regards the provisions concerning the CE marking and to end the infringement under the conditions imposed by the Director of Consumer Affairs;

9.4.2 where non-conformity continues, all appropriate measures shall be taken to restrict or prohibit the placing on the market of the product in question or to ensure that it is withdrawn from the market in accordance with the procedures laid down in regulations 7.1 to 7.4 of these regulations.

10.1 The Equipment and Protective Systems in Potentially Explosive Atmospheres Order 1999 is hereby being revoked.

Revokes L.N. 107
of 1999.

Schedule I

Based on Annex I of the Directive

CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES

1. Equipment-group I

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

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

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

- either, in the event of failure of one means of protection, at least an independent second means provides the requisite level of protection,
- or the requisite level of protection is assured in the event of two faults occurring independently of each other.

Equipment in this category must comply with the supplementary requirements referred to in point 2.0.1. of Annex II of the Directive, which is set out in Schedule II to these regulations.

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

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

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

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

Equipment in this category must comply with the supplementary requirements referred to in point 2.0.2. of Annex II of the Directive, which is set out in Schedule II to these regulations.

2. Equipment-group II

(a) Category I 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 section 2.1 of Annex II of the Directive, which is set out in Schedule II of these regulations.

(b) 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 section 2.2. of Annex II of the Directive, which is set out in Schedule II to these regulations.

(c) 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 section 2.3. of Annex II of the Directive, which is set out in Schedule II to these regulations.

Schedule II

Based on Annex II of 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 the devices referred to in regulation 2.1.1, 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 so as to be capable of coping with actual or foreseeable surrounding area conditions.

1.0.5. *Marking*

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

- name and address of the manufacturer,
- CE marking (see Annex X of the Directive, which is set out in Schedule X, section A),
- designation of series or type,
- serial number, if any,
- year of construction,
- the specific marking of explosion protection followed by the symbol of the equipment group and category,



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

and/or

the letter 'D' (concerning explosive atmospheres caused by dust).

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

1.0.6. *Instructions*

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

- a recapitulation of the information with which the equipment or protective system is marked, except for the serial number (see 1.0.5.), together with any appropriate additional information to facilitate maintenance (c.g. address of the importer, 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 be drawn up in one of the European Community languages or Maltese by the manufacturer or his authorized representative.

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On being put into service, all equipment and protective systems must be accompanied by a translation of the instructions in at least Maltese and/or English and by the instructions in the original language.

This translation must be made by either the manufacturer or his authorized representative or by the person introducing the equipment or protective system in Malta.

By way of derogation from this requirement, the maintenance instructions for use by the specialist personnel employed by the manufacturer or his authorized representative may be drawn up in a single Community language understood by that personnel.

(c) 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.

(d) 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 and 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 structures 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 releases 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 so as to:

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(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 do not give rise to dangerous situations.

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

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.

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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.

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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 I 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 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.

2.1.1.2. 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.

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2.2.2. Explosive atmospheres caused by air/dust mixtures

2.2.2.1. Equipment must be so 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 accumulations 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 III

Based on Annex III of the Directive

MODULE EC-TYPE EXAMINATION

1. This module describes that part of the procedure by which a notified body ascertains and attests that a specimen representative of the production envisaged meets the relevant applicable provisions of the regulations.

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

The application shall include:

- the name and address of the manufacturer and, if the application is lodged by the authorized representative, his name and address in addition;
- a written declaration that the same application has not been lodged with any other notified body;
- the technical documentation, as described in point 3.

The applicant shall place at the disposal of the notified body a specimen representative of the production envisaged and hereinafter called 'type'. The notified body may request further specimens if needed for carrying out the test programme.

3. The technical documentation shall enable the conformity of the product with the requirements of the regulations to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product and shall to that extent contain:

- a general type-description;
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the product;
- a list of the standards referred to in Article 5 of the Directive and regulation 6 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in Article 5 of the Directive and regulation 6 of these regulations have not been applied;

- results of design calculations made, examinations carried out, etc.;
- test reports.

4. The notified body shall:

4.1. examine the technical documentation, verify that the type has been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the relevant provisions of the standards referred to in Article 5 of the Directive and regulation 6 of these regulations, as well as the components which have been designed without applying the relevant provisions of those standards;

4.2. perform or have performed the appropriate examinations and necessary tests to check whether the solutions adopted by the manufacturer meet the essential requirements of the regulations where the standards referred to in Article 5 of the Directive and regulation 6 of these regulations have not been applied;

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

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

5. Where the type meets the provisions of the regulations, the notified body shall issue an EC-type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, conclusions of the examination and the necessary data for identification of the approved type.

A list of the significant parts of the technical documentation shall be annexed to the certificate and a copy kept by the notified body.

If the manufacturer or his authorized representative is denied a type certification, the notified body shall provide detailed reasons for such denial.

Provision shall be made for an appeals procedure.

6. The applicant shall inform the notified body which holds the technical documentation concerning the EC-type-examination certificate of all modifications to the approved equipment or protective system which must receive further approval where such changes may affect conformity with the essential requirements or with the prescribed conditions for use of the product. This further approval is given in the form of an addition to the original EC-type-examination certificate.

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

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

9. The manufacturer or his authorized representative shall keep with the technical documentation copies of EC-type-examination certificates and their additions for a period ending at least 10 years after the last equipment or protective system was manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community or Malta, the obligation to keep the technical documentation available shall be the responsibility of the person who places the product on the Community or Maltese market.

Schedule IV

Based on Annex IV of the Directive

MODULE: PRODUCTION QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of point 2 ensures and declares that the products concerned are in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the regulations which apply to them. The manufacturer, or his authorized representative, shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for EC monitoring, as specified in section 4.

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

- all relevant information for the product category envisaged;
- the documentation concerning the quality system;
- technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. The quality system shall ensure compliance of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the regulations which apply to them.

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

It shall contain, in particular, an adequate description of

- the quality objectives and the organizational structure, responsibilities and powers of the management with regard to equipment quality;
- the manufacturing, quality control and quality assurance techniques, processes and systematic actions which will be used;
- the examinations and tests which will be carried out before, during and after manufacture and the frequency with which they will be carried out;
- the quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.;
- the means to monitor the achievement of the required equipment quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard. The auditing team shall have at least one member with experience of evaluation in the equipment technology concerned. The evaluation procedure shall include an inspection visit to the manufacturer's premises. 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 uphold the system so that it remains adequate and efficient. The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

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

It shall notify its decision to the manufacturer. 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 inspection purposes, allow the notified body access to the manufacture, inspection, testing and storage premises and shall provide it with all necessary information, in particular

- the quality system documentation

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

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

4.4. Furthermore, the notified body may pay unexpected visits to the manufacturer.

During such visits, the notified body may carry out tests, or arrange for tests to be carried out, to check that the quality system is functioning correctly, if necessary. The notified body shall provide the manufacturer with a visit report and, if a test has taken place, with a test report.

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the second indent of section 3.1;

- the updating referred to in the second paragraph of section 3.4;

- the decisions and reports from the notified body which are referred to in section 3.4, last paragraph, section 4.3 and section 4.4.

6. Each notified body shall apprise the other notified bodies of the relevant information concerning the quality system approvals issued and withdrawn.

Schedule V

Based on Annex V of the Directive

MODULE: PRODUCT VERIFICATION

1. This module describes the procedure whereby a manufacturer or his authorized representative checks and attests that the equipment subject to the provisions of point 3 are in conformity with the type as described in the EC-type-examination certificate and satisfy the relevant requirements of the regulations.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees conformity of the equipment with the type as described in the EC-type-examination certificate and with the requirements of the regulations which apply to them. The manufacturer or his authorized representative shall affix the CE marking to each piece of equipment and shall draw up a declaration of conformity.

3. The notified body shall carry out the appropriate examinations and tests in order to check the conformity of the equipment, protective system or device referred to in regulation 2.1.1 of these regulations, with the relevant requirements of the regulations, by examining and testing every product as specified in section 4.

The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured.

4. Verification by examination and testing of each piece of equipment.

4.1. All equipment shall be individually examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive and regulation 6 of these regulations or equivalent tests shall be carried out in order to verify their conformity with the type as described in the EC-type-examination certificate and the relevant requirements of the regulations.

4.2. The notified body shall affix or have affixed its identification number to each approved item of equipment and shall draw up a written certificate of conformity relating to the tests carried out.

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

Schedule VI

Based on Annex VI of the Directive

MODULE: CONFORMITY TO TYPE

1. This module describes that part of the procedure whereby the manufacturer or his authorized representative ensures and declares that the equipment in question is in conformity with the type as described in the EC-type-examination certificate and satisfy the requirements of the regulations applicable to it.

The manufacturer or his authorized representative shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall take all measures necessary to ensure that the manufacturing process assures compliance of the manufactured equipment with the type as described in the EC-type-examination certificate and with the relevant requirements of the regulations.

3. The manufacturer or his authorized representative shall keep a copy of the declaration of conformity for a period ending at least 10 years after the last piece of equipment was manufactured. Where neither the manufacturer nor his authorized representative is established within the Community or Malta, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment or protective system on the Community or Maltese market.

For each piece of equipment manufactured, tests relating to the anti-explosive protection aspects of the product shall be carried out by the manufacturer or on his behalf. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

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

Schedule VII

Based on Annex VII of the Directive

MODULE: PRODUCT QUALITY ASSURANCE

1. This module describes the procedure whereby the manufacturer who satisfies the obligations of section 2 ensures and declares that the equipment is in conformity with the type as described in the EC-type-examination certificate. The manufacturer or his authorized representative shall affix the CE marking to each product and draw up a written declaration of conformity. The CE marking shall be accompanied by the identification number of the notified body responsible for surveillance as specified in section 4.

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

3. Quality system

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

The application shall include:

- all relevant information for the product category envisaged;
- documentation on the quality system;
- technical documentation on the approved type and a copy of the EC-type-examination certificate.

3.2. Under the quality system, each piece of equipment shall be examined and appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive and regulation 6 of these regulations or equivalent tests shall be carried out in order to ensure its conformity with the relevant requirements of the regulations. All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

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

- the examinations and tests which will be carried out after manufacture;
- the means to monitor the effective operation of the quality system;
- quality records, such as inspection reports and test data, calibration data, reports on the qualifications of the personnel concerned, etc.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in section 3.2. It shall presume conformity with these requirements in respect of quality systems which implement the relevant harmonized standard.

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

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 discharge the obligations arising from the quality system as approved and to maintain it in an appropriate and efficient manner.

The manufacturer or his authorized representative shall inform the notified body which has approved the quality system of any intended updating of the quality system.

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

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

4. Surveillance under the responsibility of the notified body

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

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

- quality system documentation;
- technical documentation;

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

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

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

5. The manufacturer shall, for a period ending at least 10 years after the last piece of equipment was manufactured, keep at the disposal of the national authorities:

- the documentation referred to in the third indent of section 3.1;
- the updating referred to in the second paragraph of section 3.4;
- the decisions and reports from the notified body which are referred to in section 3.4, last paragraph, section 4.3 and section 4.4.

6. Each notified body shall forward to the other notified bodies the relevant information concerning the quality system approvals issued and withdrawn.

Schedule VIII

Based on Annex VIII of the Directive

MODULE: INTERNAL CONTROL OF PRODUCTION

1. This module describes the procedure whereby the manufacturer or his authorized representative, who carries out the obligations laid down in section 2, ensures and declares that the equipment satisfies the requirements of the regulations applicable to it. The manufacturer or his authorized representative shall affix the CE marking to each piece of equipment and draw up a written declaration of conformity.

2. The manufacturer shall establish the technical documentation described in section 3 and he or his authorized representative shall keep it at the disposal of the relevant national authorities for inspection purposes for a period ending at least 10 years after the last piece of equipment was manufactured.

Where neither the manufacturer nor his authorized representative is established within the Community or Malta, the obligation to keep the technical documentation available shall be the responsibility of the person who places the equipment on the Community or Maltese market.

3. Technical documentation shall enable the conformity of the equipment with the relevant requirements of the regulations to be assessed. It shall, to the extent necessary for such assessment, cover the design, manufacture and operation of the product. It shall contain:

- a general description of the equipment,
- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of said drawings and schemes and the operation of the equipment,
- a list of the standards applied in full or in part, and descriptions of the solutions adopted to meet the safety aspects of the regulations where the standards have not been applied,
- results of design calculations made, examinations carried out, etc.,
- test reports.

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

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5. The manufacturer shall take all measures necessary to ensure that the manufacturing process guarantees compliance of the manufactured equipment with the technical documentation referred to in section 2 and with the requirements of the regulations applicable to such equipment.

Schedule IX

Based on Annex IX of the Directive

MODULE: UNIT VERIFICATION

1. This module describes the procedure whereby the manufacturer ensures and declares that the equipment or protective system which has been issued with the certificate referred to in section 2 conforms to the requirements of the regulations which are applicable to it.

The manufacturer or his authorized representative shall affix the CE marking to the equipment or protective system and draw up a declaration of conformity.

2. The notified body shall examine the individual equipment or protective system and carry out the appropriate tests as set out in the relevant standard(s) referred to in Article 5 of the Directive and regulation 6 of these regulations, or equivalent tests, to ensure its conformity with the relevant requirements of the regulations.

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

3. The aim of the technical documentation is to enable conformity with the requirements of the regulations to be assessed and the design, manufacture and operation of the equipment or protective system to be understood.

The documentation shall contain:

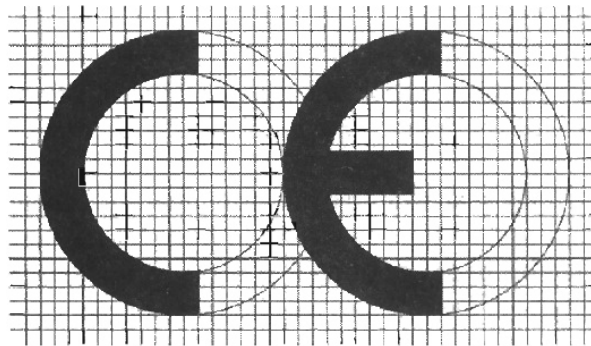
- a general description of the product;
- conceptual design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of said drawings and layouts and the operation of the equipment or protective system;
- a list of the standards referred to in Article 5 of the Directive and regulation 6 of these regulations, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the regulations where the standards referred to in Article 5 of the Directive and regulation 6 of these regulations have not been applied;
- results of design calculations made, examinations carried out, etc.;
- test reports.

Schedule X

Based on Annex X of the Directive

A. CE MARKING

The CE conformity marking shall consist of the initials "CE" in the following form:



For the avoidance of doubt, it is hereby declared that the grid providing the background in the above graduated drawing is not part of the CE marking.

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

The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5mm.

This minimum dimension may be waived for small-scale equipment, protective systems or devices referred to in regulation 2.1.1 of these regulations.

B. Content of the EC declaration of conformity

The EC declaration of conformity must contain the following elements:

- the name or identification mark and the address of the manufacturer or his authorized representative;
- a description of the equipment, protective system, or device referred to in regulation 2.1.1 of these regulations;
- all relevant provisions fulfilled by the equipment, protective system, or device referred to in regulation 2.1.1 of these regulations;
- where appropriate, the name, identification number and address of the notified body and the number of the EC-type-examination certificate;

- where appropriate, reference to the harmonised standards;
- where appropriate, the standards and technical specifications which have been used;
- where appropriate, references to other Community Directives which have been applied;
- identification of the signatory who has been empowered to enter into commitments on behalf of the manufacturer or his authorized representative.

Schedule XI

Based on Annex XI of the Directive

MINIMUM CRITERIA TO BE TAKEN INTO ACCOUNT BY MEMBER STATES FOR THE NOTIFICATION OF BODIES

1. The body, its director and the staff responsible for carrying out the verification tests shall not be the designer, manufacturer, supplier or installer of equipment, protective systems, or devices referred to in regulation 2.1.1 of these regulations which they inspect, nor the authorized representative of any of these parties. They shall become involved neither directly nor as authorized representatives in the design, construction, marketing or maintenance of the equipment, protective systems or devices referred to in regulation 2.1.1 of these regulations in question. This does not preclude the possibility of exchanges of technical information between the manufacturer and the body.

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

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

4. The staff responsible for inspection shall have:

- sound technical and professional training;
- satisfactory knowledge of the requirements of the tests which they carry out and adequate experience of such tests;
- the ability to draw up the certificates, records and reports required to authenticate the performance of the tests.

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

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

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