SUBSIDIARY LEGISLATION 427.39

EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES REGULATIONS

20th April, 2016*

LEGAL NOTICE 100 of 2016, as amended by Legal Notice 257 of 2026.

Citation and scope.

1. (1) The title of these regulations is the Equipment and Protective Systems intended for Use in Potentially Explosive Atmospheres Regulations.

(2) These regulations transpose Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the equipment and protective systems intended for use in potentially explosive atmospheres (recast).

Putting into service of products covered by the Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres Regulations, 2002.

2. (1) The making available on the market or putting into service of products covered by the Equipment and Protective Systems intended for use in Potentially Explosive Atmospheres Regulations, 2002, and which were placed on the market before the 20th April 2016 shall not be impeded.

(2) Certificates and decision by notified bodies issued under the Equipment and Protective Systems Intended For Use In Potentially Explosive Atmospheres Regulations, 2002 shall be valid under these regulations.

Applicability.

3. (1) These regulations shall apply to the following, hereinafter referred to as "products":

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

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

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

(2) These regulations shall not apply to:

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

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

(*c*) equipment intended for use in domestic and non-commercial environments where potentially explosive

* see regulation 2(1) of these Regulations as originally promulgated.

atmospheres may only rarely be created, solely as a result of the accidental leakage of fuel gas;

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

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

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

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

Definitions.
Amended by:
L.N. 257 of 2026.

4. For the purpose of these regulations, the following definitions shall apply:

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

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

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

"common specifications" means a set of technical requirements established to ensure compliance with regulatory obligations when harmonised standards are unavailable or insufficient;

"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 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;

"crisis-relevant goods" means goods that are non-substitutable, non-diversifiable or indispensable in the maintenance of vital societal functions or economic activities in order to ensure the proper functioning of the internal market and its supply chains and that are considered essential for responding to a crisis during the internal market emergency mode that may be activated pursuant to Article

18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;

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

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

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

"equipment category" means the classification of equipment, within each equipment-group, specified in Schedule I, determining the requisite level of protection to be ensured;

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

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

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

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

"implementing act" means a non-legislative act adopted by the European Commission for the purpose of providing rules and measures necessary for the implementation of these regulations and which are essential to provide for crisis situations during an internal market emergency mode activated in accordance with Article 18(4) of Regulation (EU) 2024/2747 with respect to equipment covered by these regulations;

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

"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;

"internal market emergency mode" means internal market emergency mode as defined in Article 3, point (3) of Regulation

(EU) 2024/2747;

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

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

"national accreditation body" means national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

"notified body" means a conformity assessment body which has been officially designated by its national authority and notified to the Commission to carry out the procedures for conformity assessment of certain products in accordance with regulation 15 before being placed on the market;

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

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

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

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

"Regulation (EU) 2024/2747" means Regulation (EU) 2024/2747 of the European Parliament and of the Council of 9 October 2024 establishing a framework of measures related to an internal market emergency and to the resilience of the internal market and amending Council Regulation (EC) No 2679/98 (Internal Market Emergency and Resilience Act);

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

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

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

Making available on the market and putting into service.

5. (1) Products falling within the scope of these regulations may be made available on the market and put into service only if, they are properly installed and maintained and used in accordance with their intended use,

(2) The provisions of these regulations shall not prevent from laying down any requirements deemed necessary to ensure that persons and, in particular, workers are protected when using relevant products provided that this does not mean that such

products are modified in a way not specified in these regulations.

(3) At trade fairs, exhibitions and demonstrations, the showing of products which do not comply with these regulations shall not be prevented, provided that a visible sign clearly indicates that such products do not comply with these regulations and that they are not for sale until they have been brought into conformity by the manufacturer. During demonstrations, adequate safety measures shall be taken to ensure the protection of persons.

Essential health and safety requirements.

6. Products shall meet the essential health and safety requirements set out in Schedule II which apply to them, account being taken of their intended use.

Free movement.

7. The making available on the market and putting into service in Malta of products which comply with these regulations shall not be prohibited, restricted or impeded.

Obligations of the manufacturer.

8. (1) When placing their products on the market or using them for their own purposes, manufacturers shall ensure that they have been designed and manufactured in accordance with the essential safety requirements set out in Schedule I.

(2) Manufacturers shall draw up the technical documentation referred to in Schedule II to IX and carry out the relevant conformity assessment procedure referred to in regulation 15.Where compliance of a product, other than a component, with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking. Where compliance of a component with the applicable requirements has been demonstrated by the relevant conformity assessment procedure, manufacturers shall draw up a written attestation of conformity as referred to in regulation 15(3). Manufacturers shall ensure that each product is accompanied by a copy of the EU declaration of conformity or of the attestation of conformity, as appropriate. However, where a large number of products are delivered to a single user, the batch or consignment concerned may be accompanied by a single copy.

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

(4) Manufacturers shall ensure that procedures are in place for series production to remain in conformity with these regulations. Changes in a product design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of a product is declared shall be adequately taken into account. When deemed appropriate with regard to the risks presented by a product, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

(5) Manufacturers shall ensure that products which they have

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

(6) Manufacturers shall ensure that products, other than components, which they have placed on the market bear the specific marking of explosion protection and, where applicable, the other markings and information referred to in point 1.0.5 of Schedule II.

(7) Manufacturers shall indicate, on the product, their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in at least the Maltese or English language.

(8) Manufacturers shall ensure that the product is accompanied by instructions and safety information in at least the Maltese or English language. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

(9) Manufacturers who consider or have reason to believe that a product which they have placed on the market is not in conformity with these regulations shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, manufacturers shall immediately inform the Technical Regulations Division, giving details, in particular, of the non-compliance and of any corrective measures taken.

(10) Manufacturers shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the product with these regulations, in at least the Maltese and English language. They shall cooperate with the Technical Regulations Division, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Authorised representatives.

9. (1) A manufacturer may, by a written mandate, appoint an authorised representative. The obligations laid down in regulation 8(1) and the obligation to draw up technical documentation referred to in regulation 8(2) shall not form part of the authorised representative's mandate.

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

(*a*) keep the EU declaration of conformity or, where applicable, the attestation of conformity and the technical documentation at the disposal of national

market surveillance authorities for 10 years after the product has been placed on the market;

(*b*) further to a reasoned request from the Technical Regulations Division, provide the Technical Regulations Division with all the information and documentation necessary to demonstrate the conformity of a product;

(*c*) cooperate with the Technical Regulations Division, at their request, on any action taken to eliminate the risks posed by products covered by the authorised representative's mandate.

Obligations of importers.

10. (1) Importers shall place only compliant products on the market.

(2) Before placing a product on the market importers shall ensure that the appropriate conformity assessment procedure referred to in regulation 15 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the product bears the CE marking, where applicable, is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents, and that the manufacturer has complied with the requirements set out in regulations 8(5), (8) and (9).

Where an importer considers or has reason to believe that a product is not in conformity with the essential health and safety requirements set out in Schedule II, he shall not place the product on the market until it has been brought into conformity. Furthermore, where the product presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

(3) Importers shall indicate on the product their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the product. The contact details shall be in at least the Maltese or English language.

(4) Importers shall ensure that the product is accompanied by instructions and safety information in at least the Maltese or English language.

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

(6) When deemed appropriate with regard to the risks presented by a product, importers shall, to protect the health and safety of end-users, carry out sample testing of products made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming products and product recalls, and shall keep distributors informed of any such monitoring.

(7) Importers who consider or have reason to believe that a product which they have placed on the market is not in conformity

with these regulations shall immediately take the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the product presents a risk, importers shall immediately inform the Technical Regulations Division to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(8) Importers shall, for 10 years after the product has been placed on the market, keep a copy of the EU declaration of conformity or, where applicable, of the attestation of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to the Technical Regulations Division, upon request.

(9) Importers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product in at least the Maltese or English language. They shall cooperate with the Technical Regulations Division, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.

Obligations of distributors.

11. (1) When making a product available on the market distributors shall act with due care in relation to the requirements of these regulations.

(2) Before making a product available on the market distributors shall verify that the product bears the CE marking, where applicable, that it is accompanied by the EU declaration of conformity or the attestation of conformity and the required documents and by instructions and safety information, in at least the Maltese and English language, and that the manufacturer and the importer have complied with the requirements set out in regulation 8(5), (6) and (7) and regulation 10(3) respectively.

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

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

(4) Distributors who consider or have reason to believe that a product which they have made available on the market is not in conformity with these regulations shall make sure that the corrective measures necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the product presents a risk, distributors shall immediately inform the Technical Regulations Division in which

they made the product available on the market to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

(5) Distributors shall, further to a reasoned request from the Technical Regulations Division, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product. They shall cooperate with the Technical Regulations Division, at its request, on any action taken to eliminate the risks posed by products which they have made available on the market.

Cases in which obligations of manufacturers apply to importers and distributors.

12. An importer or distributor shall be considered a manufacturer for the purposes of these regulations and he shall be subject to the obligations of the manufacturer under regulation 4, where he places a product on the market under his name or trade mark or modifies a product already placed on the market in such a way that compliance with these regulations may be affected.

Identification of economic operators.

13. (1) Economic operators shall, on request, identify the following to the market surveillance authorities:

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

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

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

Presumption of conformity of products.

14. (1) Products which are in conformity with harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the essential health and safety requirements set out in Schedule II covered by those standards or parts thereof.

(2) In the absence of harmonised standards, the Technical Regulations Division shall take any steps which they deem necessary to bring to the attention of the parties concerned the existing national standards and technical specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements set out in Schedule II.

Conformity assessment procedures.

15. (1) The procedures to be followed for assessing the conformity of equipment and, where necessary, the devices referred to in paragraph (*b*) of regulation 3(1) shall be as follows:

(*a*) for equipment-groups I and II, equipment-categories M1 and 1, the EU-type examination set out in Schedule III, in conjunction with either of the following:

(i) conformity to type based on quality assurance of the production process set out in Schedule IV,

(ii) conformity to type based on product verification

set out in Schedule V;

(*b*) for equipment-groups I and II, equipment categories M2 and 2:

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

- conformity to type based on internal production control plus supervised product testing set out in Schedule VI,
- conformity to type based on product quality assurance set out in Schedule VII;

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

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

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

(2) The procedure referred to in paragraphs (*a*) or (*d*) of sub-regulation (1) shall be used for conformity assessment of protective systems.

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

(4) With regard to the safety aspects referred to in point 1.2.7 of Schedule II, in addition to the conformity assessment procedures referred to in sub-regulations (1) and (2), the procedure referred to in Schedule VIII may also be followed.

(5) By derogation from sub-regulations (1), (2) and (4), the Technical Regulations Division may, on a duly justified request, authorise the placing on the market and putting into service on the territory of the Malta concerned of the products other than components in respect of which the procedures referred to in sub-regulations (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 sub-regulations (1) to (4) shall be drawn up in at least the Maltese and English language.

EU declaration of conformity.

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

(2) The EU declaration of conformity shall have the model structure set out in Schedule X, shall contain the elements specified in the relevant conformity assessment procedures set out in Schedules III to IX and shall be continuously updated. It shall be translated into at least the Maltese or English language.

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

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

CE marking.

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

(2) The CE marking shall be affixed visibly, legibly and indelibly to the product or to its data plate. Where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging and to the accompanying documents.

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

(4) The CE marking shall be followed by the identification number of the notified body, where that body is involved in the production control phase. The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

(5) The CE marking and, where applicable, the identification number of the notified body shall be followed by the specific marking of explosion protection , the symbols of the equipment-group and category and, where applicable, the other markings and information referred to in point 1.0.5 of Schedule II.

(6) The CE marking and the markings, symbols and information referred to in sub-regulation (4), and, where applicable, the identification number of the notified body, may be followed by any other mark indicating a special risk or use. Products that are designed for a particular explosive atmosphere shall be marked accordingly.

(7) The Technical Regulations Division shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notification Of Conformity Assessment Bodies.

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

(2) The Technical Regulations Division shall responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with the provisions of regulations 19(3) to 19(16).

(3) The assessment and monitoring referred to in sub-regulation (2) shall be carried out by the National Accreditation Board (Malta).

(4) The Technical Regulations Division shall take full responsibility for the tasks performed by National Accreditation Board (Malta) referred to in sub-regulation (3).

(5) The Technical Regulations Division shall inform the European Commission of its procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

Requirements relating to notified bodies.

S.L. 427.45.

19. (1) For the purposes of notification under these regulations, a conformity assessment body shall meet the requirements laid down in sub-regulations (2) to (16) and in the Method for Designating Conformity Assessment Bodies Regulations.

(2) A conformity assessment body shall be established under Maltese law and have legal personality.

(3) A conformity assessment body shall be a third-party body independent of the organisation or the product it assesses. A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

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

(*b*) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture or construction, the marketing, installation, use or

maintenance of those products, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

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

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

(6) (*a*) A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Schedules III to VII and Schedules IX and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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

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

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

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

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

(7) The personnel responsible for carrying out conformity assessment tasks shall have the following:

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

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

(*c*) appropriate knowledge and understanding of the essential health and safety requirements set out in Schedule II, of the applicable harmonised standards, of the relevant provisions of Union harmonisation legislation and of national legislation;

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

(8) The impartiality of the conformity assessment bodies, their top level management, and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed. The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

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

(10) The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Schedules III to VII and Schedule IX or any provision of national law giving effect to it, except in relation to the Technical Regulations Division. Proprietary rights shall be protected.

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

(12) Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the Official Journal of the European Union, it shall be presumed to comply with the requirements set out in regulation 19 in so far as the applicable harmonised standards cover those requirements.

(13) Where a notified body subcontracts specific tasks

connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in regulation 19 and shall inform the Technical Regulations Division accordingly.

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

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

(16) Notified bodies shall keep at the disposal of the Technical Regulations Division the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Schedules III to VII and Schedule IX.

Notification procedures.

20. (1) A conformity assessment body established in Malta shall submit an application for notification to the Technical Regulations Division.

(2) The application referred to in the preceding sub-regulation shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which that body claims to be competent, as well as by an accreditation certificate, issued by the National Accreditation Board (Malta) attesting that the conformity assessment body fulfils the requirements laid down in regulation 19 and the Method for Designating Conformity Assessment Bodies Regulations. S.L. 427. 45.

(3) The Technical Regulations Division may notify only conformity assessment bodies which have satisfied the requirements laid down in regulation 19 and the Method for Designating Conformity Assessment Bodies Regulations. S.L. 427. 45.

(4) The Technical Regulations Division shall notify conformity assessment bodies to the European Commission and the other Member States using the electronic notification tool developed and managed by the European Commission.

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

(6) The body concerned may perform the activities of a notified body only where no objections are raised by the European Commission or the other Member States within two weeks of a notification. Only such a body shall be considered a notified body for the purposes of these regulations.

(7) The Technical Regulations Division shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification.

(8) Where the Technical Regulations Division has ascertained or has been informed that a notified body no longer meets the requirements laid down in regulation 19 or the Method for Designating Conformity Assessment Bodies Regulations, or that it is failing to fulfil its obligations, the Technical Regulations Division shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the European Commission and the other Member States accordingly.

S.L. 427. 45.

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

(10) The Technical Regulations Division shall provide the European Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

Operational obligations of notified bodies.

21. (1) Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Schedules III to VII and Schedule IX.

(2) Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process. In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the product with the requirements of these regulations.

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

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

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

(6) Notified bodies shall inform the notifying authority of the following:

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

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

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

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

(7) Notified bodies shall provide the other bodies notified under these regulations carrying out similar conformity assessment activities covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

(8) Notified bodies shall participate, directly or by means of designated representatives, in the appropriate coordination and cooperation groups for notified bodies organised by the European Commission.

Market surveillance.

22. (1) Regulation 15(3) and regulations 16 to 29 of regulation (EC) No 765/2008 shall apply to products covered by Schedule 1 of these regulations.

(2) Where the market surveillance authorities have sufficient reason to believe that a product presents a risk to the health or safety of persons or to domestic animals or property, they shall carry out an evaluation in relation to the product concerned covering all relevant requirements laid down in these regulations. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

(3) Where, in the course of the evaluation referred to sub-regulation (1), the market surveillance authorities find that the product does not comply with the requirements laid down in these regulations, they shall 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 they may prescribe.The market surveillance authorities shall inform the relevant notified body accordingly.

(4) Regulation 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the sub-regulation (3).

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

(6) The economic operator shall ensure that all appropriate corrective action is taken in respect of all the products concerned

that it has made available on the market throughout the Union.

(7) Where the relevant economic operator does not take adequate corrective action within the period referred to in sub-regulation (3), the Technical Regulations Division shall take all appropriate provisional measures to prohibit or restrict the products being made available on their national market, to withdraw the product from that market or to recall it. The market surveillance authorities shall inform the European Commission and the other Member States, without delay, of those measures.

(8) The information referred to in the regulation 8 shall include all available details, in particular the data necessary for the identification of the non-compliant product, the origin of the product, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the Technical Regulations Division shall indicate whether the non-compliance is due to either of the following:

(*a*) 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

(*b*) shortcomings in the harmonised standards referred to in regulation 14 conferring a presumption of conformity.

(9) When the procedure under this Regulation is initiated by another Member State, the Technical Regulations Division, shall without delay inform the European Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of product concerned, and, in the event of disagreement with the adopted national measure, of their objections.

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

(11) In such cases, the Technical Regulations Division 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.

(12) Where on completion of the procedure set out in sub-regulations (6) and (7), objections are raised against the measures taken by Technical Regulations Division; the European Commission shall conduct an evaluation including appropriate consultations with these entities and the relevant economic operator or operators.

(13) If, on the basis of this evaluation, the national measure is considered justified, the Technical Regulations Division shall take the necessary measures to ensure that the placing on the market or use non-compliant product is withdrawn from the Maltese market, and shall inform the European Commission accordingly. If, on the

basis of this evaluation, the national measure is considered unjustified, the national measure shall be withdraw.

(14) Where, having carried out an evaluation under sub-regulation (2), the Technical Regulations Division finds that although a product is in compliance with these Regulations, it presents a risk to the health or safety of persons or to domestic animals or property, it shall require the relevant economic operator to take all appropriate measures to ensure that the product concerned, when placed on the market, no longer presents that risk, to withdraw the product from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

(15) The economic operator shall ensure that corrective action is taken in respect of all the products concerned that he has made available on the market throughout the European Union.

(16) The Technical Regulations Division, upon consultation with the Commissioner of Police, shall immediately inform the European Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the product concerned, the origin and the supply chain of the product, the nature of the risk involved and the nature and duration of the national measures taken.

(17) Without prejudice to sub-regulations (2) to (11), where the Technical Regulations Division and/or the Commissioner of Police makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

(*a*) the CE marking has been affixed in violation of article 30 of Regulation (EC) No 765/2008 or of regulation 17 of these regulations;

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

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

(*d*) the identification number of the notified body, where that body is involved in the production control phase, has been affixed in violation of regulation 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 regulation 8(7) or 10(3) is absent, false or incomplete;

(*i*) any other administrative requirement provided for in regulation 8 or 10 is not fulfilled.

(19) Where the non-compliance referred to in sub-regulation (1) persists, the Technical Regulations Division concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or ensure that it is recalled or withdrawn from the Maltese market.

Application of emergency procedures. *Added by: L.N. 257 of 2026.*

22A. (1) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 22B to 22E apply only during the activation of the internal market emergency procedure in accordance with Article 28 of Regulation (EU) 2024/2747 and by means of an implementing act pursuant to Article 18(4) of Regulation (EU) 2024/2747 with respect to products covered by these regulations. The emergency procedures relevant to Union harmonisation legislation may be activated as regards those crisis-relevant goods as defined by these regulations.

(2) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 22B to 22E apply only to products which have been designated as crisis-relevant goods in accordance with Article 18(4) of Regulation (EU) 2024/2747.

(3) The Technical Regulations Division shall ensure that measures taken in accordance with regulations 22B to 22E apply only during the internal market emergency mode which has been activated in accordance with Article 18 of Regulation (EU) 2024/2747:

Provided that regulation 22C(6) shall apply during the internal market emergency mode and after its expiry or deactivation.

Prioritisation of the conformity assessment of products designated as crisis-relevant goods. *Added by: L.N. 257 of 2026.*

22B. (1) The provisions of this regulation shall apply to all products referred to in regulation 22A(1) which are subject to the conformity assessment procedures referred to in regulation 15 and which require mandatory involvement of a notified body.

(2) The notified bodies shall as a matter of priority, take all appropriate measures to process all applications for a conformity assessment of products referred to in sub-regulation (1), irrespective of whether those applications have been filed before or after the activation of the emergency procedures.

(3) The prioritisation of applications for a conformity assessment of products in accordance with sub-regulation (2) shall not result in additional disproportionate costs for the manufacturers who have filed those applications.

(4) The notified bodies shall take all reasonable measures to increase their testing capacities for products referred to sub-regulation (1) in respect of which they have been notified.

Derogation from the conformity assessment procedures requiring the mandatory involvement of a notified body. *Added by: L.N. 257 of 2026.*

22C. (1) By way of derogation from regulation 15, the Technical Regulations Division may authorise, following a duly justified request from an economic operator, the placing on the market or use for the manufacturer's own purposes in Malta, of a specific product for which the conformity assessment procedures referred to in regulation 15 which require the mandatory involvement of a notified body have not been carried out:

Provided that compliance with all the applicable essential health and safety requirements established in Schedule II has been demonstrated in accordance with procedures referred to in such authorisation. The Technical Regulations Division shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with this sub-regulation.

(2) The product subject to the extension of validity of the authorisation referred to in sub-regulation (1) shall bear the information that it is placed on the market or used for the manufacturer's own purposes as a crisis-relevant good. Such information, as well as any labelling shall be clear, intelligible, and where relevant, shall be written in the English or Maltese language.

(3) The authorisation granted by Technical Regulations Division in accordance with sub-regulation (1) shall be valid only in Malta unless it has been recognised as valid by a national market surveillance authority in another Member State. The Technical Regulations Division shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.

(4) Manufacturers of products subject to the authorisation procedure referred to in sub-regulation (1) shall declare on their sole responsibility that the product concerned complies with all the applicable essential health and safety requirements established in Schedule II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the Technical Regulations Division.

(5) Any authorisation issued in accordance with sub-regulation (1) shall establish the conditions and requirements under which the product may be placed on the market or used for the manufacturer's own purposes. Such authorisations shall establish at least the following:

(a) a description of the procedures by means of which compliance with the applicable essential health and safety requirements established in Schedule II was successfully demonstrated;

(b) any specific requirements regarding the traceability of the product concerned;

(c) an end date of validity of the authorisation, which shall not go beyond the last day of the period for which the internal market emergency mode has been activated in accordance with Article 18 of Regulation (EU) 2024/2747;

(d) any specific requirements regarding the need to ensure a continuous conformity assessment with respect to the product concerned;

(e) measures to be taken upon expiry or deactivation of the internal market emergency mode with respect to the products concerned that have been placed on the market or used for the manufacturer's own purposes.

(6) By way of derogation from regulations 9 and 17, products for which an authorisation has been granted in accordance with sub-regulation (1) shall not bear the CE marking and regulation 9 shall not apply.

(7) Where an authorisation pursuant to sub-regulations (1) and (3) is valid, the Technical Regulations Division shall with respect to such products take all corrective and restrictive actions provided for under the Market Surveillance and Compliance of Products Regulations and these regulations. The Technical Regulations Division shall immediately inform the Commission and the market surveillance authorities of all other Member States of these actions.

S.L. 427.105.

(8) The use of the authorisation procedure established in sub-regulations (1) and (2) shall not affect the application of the relevant conformity assessment procedures stipulated in regulation 15.

Presumption of conformity based on harmonised standards and common specifications. *Added by: L.N. 257 of 2026.*

22D. (1) Without prejudice to regulation 17, products which are in conformity with the standards or common specifications or parts thereof referred to in these regulations, shall be presumed to be in conformity with the applicable essential health and safety requirements established in Schedule II which are covered by those standards, common specifications or parts thereof.

(2) From the day following the expiry or deactivation of the internal market emergency mode, it shall no longer be possible for manufacturers to rely on the presumption of conformity provided by the harmonised standards, or the common specifications referred to in sub-regulation (1).

(3) By way of derogation from regulation 22A(3), unless there is sufficient reason to believe that the products covered by the harmonised standards or common specifications referred to in sub-regulation (1) present a risk to the health or safety of persons, the products which are in conformity with those standards or common specifications and which have been placed on the market shall be deemed to be in conformity with the applicable essential health and safety requirements established in Schedule II after the expiry or deactivation of the internal market emergency mode.

(4) When the Technical Regulations Division considers that a standard or common specification as referred to in sub-regulation (1) does not entirely satisfy the relevant essential health and safety requirements specified in Schedule I, it shall inform the Commission by submitting a detailed explanation thereof.

22E. The Technical Regulations Division shall provide assistance to other market surveillance authorities during an internal market emergency mode, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support.

Prioritisation of market surveillance activities and mutual assistance among authorities. *Added by: L.N. 257 of 2026.*

23. The penalties applicable for the infringement of any of the provisions of these regulations shall be those provided for in Part IV of the Product Safety Act.

Penalties.

Cap. 427.

Schedule I

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 II.

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

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

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

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

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

2. **Equipment-group II**

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

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

Equipment in this category must ensure the requisite level of protection, even in the event of rare incidents relating to equipment, and is

characterised by means of protection such that:

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

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

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

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

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 II.

(*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 II.

Schedule II

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 point (b) of Article 1(1), the essential health and safety 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 Schedule 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), 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 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 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. Safeopening

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 do 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. Flame proof 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 equipment-group I*

2.0.1. Requirements applicable to equipment category M1 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, 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 category M2 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 equipment category M 1 must be applied.

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

2.1.1. Explosive atmospheres caused by gases, vapoursormists

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 applicable to equipment category 2 of equipment-group II.

2.2.1. Explosive atmospheres caused by gases, vapoursormists.

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 cause 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 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

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 these regulations 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*) possible to assess the product's conformity the technical documentation. The technical documentation shall make it with the applicable requirements of these regulations 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 description of the product,

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

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

(iv) 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 these regulations, 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,

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

(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 these regulations;

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

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

6. Where the type meets the requirements of these regulations 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 Schedules attached.

The EU-type examination certificate and its Schedules 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 these regulations, 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 these regulations, 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 these regulations 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 Schedules 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 Schedules 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 IV

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 these regulations that apply to them.

2. **Manufacturing**

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

3. **Quality system**

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

The application shall include:

(*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 that the products are in conformity with the type described in the EU-type examination certificate and comply with the requirements of these regulations that apply to them.

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

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

(*a*) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality,

(*b*) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used,

(*c*) the examinations and tests that 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, qualification reports on the personnel concerned, etc., and

(*e*) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it

satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the 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 these regulations. 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 these regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

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

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

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

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

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

4. **Surveillance under the responsibility of the notified body**

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

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

(*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 these regulations.

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 V

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 these regulations 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 these regulations 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 these regulations.

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 these regulations.

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 these regulations.

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. If the notified body agrees and under its responsibility, the manufacturer

may affix the notified body's identification number to the products during the manufacturing process.

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 VI

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 these regulations 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 these regulations 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 these regulations. 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 these regulations.

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 VII

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 these regulations that apply to them.

2. **Manufacturing**

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

3. **Quality system**

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

The application shall include:

(*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 these 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. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

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

(*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, qualification 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 point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the 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 these regulations. 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 these regulations and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

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

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

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

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

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

4. **Surveillance under the responsibility of the notified body**

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

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

(*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 these regulations.

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 VIII

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 these regulations 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 these regulations, 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 these regulations 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 these regulations.

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 IX

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 these regulations 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 these regulations, 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 these regulations.

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 these regulations, 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 these regulations.

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 X

EU DECLARATION OF CONFORMITY (No XXXX) (*)

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

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

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

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

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

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

7. Where applicable, the notified body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

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