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 equipment and protective systems intended for use in potentially explosive atmospheres (recast) (Text with EEA relevance)

ANNEX 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 Annex II.

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

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

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

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

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

2. **Equipment-group II**

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

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

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

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

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

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

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

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

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 Annex 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 Annex II.

ANNEX 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 Annex II to Regulation (EC) No 765/2008),

— designation of series or type,

— batch or serial number, if any,

— year of construction,

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

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

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 structures and prevention of leaks*

Equipment which may release flammable gases or dusts must wherever possible employ enclosed structures only.

If equipment contains openings or non-tight joints, these must as far as possible be designed in such a way that releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.

Points where materials are introduced or drawn off must, as far as possible, be designed and equipped so as to limit releases of flammable materials during filling or draining.

1.2.4. *Dust deposits*

Equipment and protective systems which are intended to be used in areas exposed to dust must be so designed that deposit dust on their surfaces is not ignited.

In general, dust deposits must be limited where possible. Equipment and protective systems must be easily cleanable.

The surface temperatures of equipment parts must be kept well below the glow temperature of the deposit dust.

The thickness of deposit dust must be taken into consideration and, if appropriate, means must be taken to limit the temperature in order to prevent a heat build up.

1.2.5. *Additional means of protection*

Equipment and protective systems which may be exposed to certain types of external stresses must be equipped, where necessary, with additional means of protection.

Equipment must withstand relevant stresses, without adverse effect on explosion protection.

1.2.6. *Safe opening*

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

1.2.7. *Protection against other hazards*

Equipment and protective systems must be so designed and manufactured 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, this Directive shall not apply or shall cease to apply in the case of such equipment and protective systems and of such risks upon application of that specific Union legislation.

1.2.8. *Overloading of equipment*

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

1.2.9. *Flameproof enclosure systems*

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

1.3. *Potential ignition sources*

1.3.1. *Hazards arising from different ignition sources*

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

1.3.2. *Hazards arising from static electricity*

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

1.3.3. *Hazards arising from stray electric and leakage currents*

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

1.3.4. *Hazards arising from overheating*

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

1.3.5. *Hazards arising from pressure compensation operations*

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

1.4. *Hazards arising from external effects*

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

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

1.5. *Requirements in respect of safety-related devices*

1.5.1. Safety devices must function independently of any measurement and/or control devices required for operation.

As far as possible, failure of a safety device must be detected sufficiently rapidly by appropriate technical means to ensure that there is only very little likelihood that dangerous situations will occur.

The fail-safe principle is to be applied in general.

Safety-related switching must in general directly actuate the relevant control devices without intermediate software command.

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

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

1.5.4. *Control and display units*

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

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

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

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

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

1.5.8. *Risks arising from software*

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

1.6. *Integration of safety requirements relating to the system*

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

1.6.2. When the emergency shutdown system is actuated, accumulated energy must be dispersed as quickly and as safely as possible or isolated so that it no longer constitutes a hazard.

This does not apply to electrochemically-stored energy.

1.6.3. *Hazards arising from power failure*

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

1.6.4. *Hazards arising from connections*

Equipment and protective systems must be fitted with suitable cable and conduit entries.

When equipment and protective systems are intended for use in combination with other equipment and protective systems, the interface must be safe.

1.6.5. *Placing of warning devices as parts of equipment*

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

2. **Supplementary requirements in respect of equipment**

2.0. *Requirements applicable to equipment in equipment-group I*

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

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

Equipment must be equipped with means of protection such that:

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

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

Where necessary, 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 M 2 of equipment-group I*

2.0.2.1. Equipment must be equipped with means of protection ensuring that sources of ignition do not become active during normal operation, even under more severe operating conditions, in particular those arising from rough handling and changing environmental conditions.

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

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

2.0.2.3. The requirements regarding explosion hazards arising from dust applicable to 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, vapours or mists*

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

It must be equipped with means of protection such that:

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

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

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

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

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

If necessary, equipment must be fitted with appropriate additional interlocking systems.

2.1.2. *Explosive atmospheres caused by air/dust mixtures*

2.1.2.1. Equipment must be so designed and constructed that ignition of air/dust mixtures does not occur even in the event of rare incidents relating to equipment.

It must be equipped with means of protection such that

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

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

2.1.2.2. Where necessary, equipment must be so designed that dust can enter or escape from the equipment only at specifically designated points.

This requirement must also be met by cable entries and connecting pieces.

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

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

2.2. *Requirements applicable to equipment category 2 of equipment-group II*

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

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

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

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

2.2.2. *Explosive atmospheres caused by air/dust mixtures*

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

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

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

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

2.3. *Requirements applicable to equipment 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.

ANNEX 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 this Directive that apply to it.

2. EU-type examination shall be carried out with the examination of a specimen, representative of the production envisaged, of the complete product (production type).

3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

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

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

(c) the technical documentation. The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of this Directive and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

  (i) a general 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 this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,

  (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 this Directive;

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 this Directive that apply to the product concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of this Directive, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself 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 this Directive, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential health and safety requirements of this Directive or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

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

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-

type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

ANNEX 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 this Directive 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 this Directive 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 this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

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

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to 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 this Directive.

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

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

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

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

(a) the documentation referred to in point 3.1,

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

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX 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 this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Verification**

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

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

4. **Verification of conformity by examination and testing of every product**

4.1. All products shall be individually examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications, shall be carried out in order to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of this Directive.

In the absence of such a harmonised standard, the notified body concerned shall decide on the appropriate tests to be carried out.

4.2. The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out, and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the product has been placed on the market.

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

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

in the EU-type examination certificate and satisfies the applicable requirements of this Directive.

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

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

If the notified body referred to in point 3 agrees and under its responsibility, the manufacturer may also affix the notified body's identification number to the products other than components.

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

6. 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.

ANNEX 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 this Directive that apply to them.

2. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the EU-type examination certificate and with the requirements of this Directive that apply to them.

3. **Product checks**

For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer or on his behalf, in order to verify conformity with the type described in the EU-type examination certificate and with

the corresponding requirements of this Directive. The tests shall be carried out under the responsibility of a notified body, chosen by the manufacturer.

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

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

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

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

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

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

5. **Authorised representative**

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX 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 this Directive 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 this Directive.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and 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 this Directive. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation referred to in point 3.1(e) in order to verify the manufacturer's ability to identify the relevant requirements of this Directive and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be notified to the manufacturer. The notification shall contain the conclusions of the 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 this Directive.

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

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

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

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

(a) the documentation referred to in point 3.1,

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

(c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.

7. Each notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

8. **Authorised representative**

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX 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 this Directive that apply to them.

2. **Technical documentation**

The manufacturer shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s).

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

(a) a general description of the product,

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

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

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

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

(f) test reports.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of this Directive that apply to them.

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

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

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

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

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

5. **Authorised representative**

The 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.

ANNEX 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 this Directive that apply to it.

2. **Technical documentation**

2.1. The manufacturer shall establish the technical documentation and make it available to the notified body referred to in point 4. The documentation shall make it possible to assess the product's conformity with the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

(a) a general description of the product,

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

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

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

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

(f) test reports.

2.2. The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

3. **Manufacturing**

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of this Directive.

4. **Verification**

A notified body chosen by the manufacturer shall carry out appropriate examinations and tests, set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of this Directive, or have them carried out. In the absence of such a harmonised standard the notified body concerned shall decide on the appropriate tests to be carried out.

The notified body shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

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

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

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

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

5.3. The manufacturer shall draw up a written attestation of conformity and keep it at the disposal of the national authorities for 10 years after the component has been placed

on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

6. **Authorised representative**

The 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.

ANNEX X

EU DECLARATION OF CONFORMITY (No XXXX)[1]

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):

ANNEX XI

PART A

REPEALED DIRECTIVE WITH LIST OF THE SUCCESSIVE AMENDMENTS THERETO

(referred to in Article 43)

Directive 94/9/EC of the European Parliament and of the Council	

(OJ L 100, 19.4.1994, p. 1).	
Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).	Only point 8 of Annex I
Regulation (EU) No 1025/2012 of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).	Only point (c) of Article 26(1)

PART B

TIME LIMITS FOR TRANSPOSITION INTO NATIONAL LAW AND DATES OF APPLICATION

(referred to in Article 43)

Directive	**Time limit for transposition**	**Date of application**
94/9/EC	1 September 1995	1 March 1996

ANNEX XII

CORRELATION TABLE

Directive 94/9/EC	**This Directive**
Article 1(1)	Article 1(1)(a)
Article 1(2)	Article 1(1)(b)
—	Article 1(1)(c)
Article 1(3)	Article 2(1) to (9)
—	Article 2(10) to (26)
Article 1(4)	Article 1(2)
Article 2	Article 3
Article 3	Article 4
Article 4	Article 5
Article 5(1), first subparagraph	—
Article 5(1), second subparagraph	Article 12(2)
Article 5(2)	Article 12(1)
Article 5(3)	—
—	Articles 6 to 11
—	—
Article 6(1) and (2)	—

Article 6(3)	Article 39(1) to (4)
—	Article 39(5), first subparagraph
Article 6(4)	Article 39(5), second subparagraph
Article 7	—
Article 8(1) to (6)	Article 13(1) to (6)
Article 8(7)	—
—	Articles 14 and 15
Article 9	—
Article 10(1)	—
Article 10(2)	Article 16(1)
Article 10(3)	—
—	Article 16(2) to (6)
—	Articles 17 to 33
Article 11	—
—	Articles 34 to 38
Articles 12 and 13	—
—	Article 40
—	Article 41(1)
Article 14(1)	—
Article 14(2)	Article 41(2)
Article 14(3)	—
Article 15(1)	Article 42(1)
Article 15(2)	—
—	Article 42(2)
—	Articles 43 and 44
Article 16	Article 45
Annexes I to IX	Annexes I to IX
Annex X	—
Annex XI	—
—	Annex X
—	Annex XI
—	Annex XII

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