# THE RULEBOOK

# ON THE EQUIPMENT AND PROTECTIVE SYSTEMS INTENDED FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERES

*("Official Gazette of Republic of Serbia", NO 10/2017 and 21/2020)*

## I. INTRODUCTORY PROVISIONS

### Subject matter

### Article 1

This Rulebook prescribes: the essential health and safety requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres, as well as other requirements and conditions that must be met for their supply on the market and putting into service; groups and categories of equipment intended for use in potentially explosive atmospheres; the conformity assessment procedures; the declaration of conformity and model of declaration of conformity; the contents of technical documentation; marking, conformity marking and marking of explosion protection; the safeguard clause, and requirements that must be fulfiled by the conformity assessment body in order to be designated for conformity assessment.

### Scope

### Article 2

This Rulebook shall apply to the following equipment, protective systems, devices and components (hereinafter referred to as: the products):

1) The equipment and protective systems intended for use in potentially explosive atmospheres;

2) The 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;

3) The components intended to be incorporated into equipment and protective systems referred to in point 1) of this Article.

### The products excluded from the scope of this Rulebook

**Article 3**

This Rulebook shall not apply to the following products:

1) The medical devices intended for use in medical environment;

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

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

4) The personal protective equipment covered by legislation governing safety and other technical requirements for personal protective equipment;

5) The seagoing vessels and mobile offshore units together with equipment on board such vessels or units;

6) The 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, with the exception of vehicles intended for use in explosive atmosphere;

7) The military armament, including ammunition and equipment intended to be used exclusively as military equipment.

**Definitions**

**Article 4**

Certain terms used in this Rulebook shall have the following meaning:

1) *The equipment* means the 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;

2) *The 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;

3) *The component* means any item essential to the safe functioning of equipment and protective systems but with no autonomous function;

4) *The 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;

5) *The potentially explosive atmosphere* means an atmosphere which could become explosive due to local and operational conditions;

6) *The equipment group I* means the 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 Annex 1– Criteria for the classification of equipment groups into categories, which is printed together with this Rulebook as its integral part;

7) *The equipment group II* means the equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 as set out in Annex I;

8) *The equipment category* means the classification of equipment, within each equipment group, specified in Annex I, determining the requisite level of protection to be ensured;

9) The *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;

10) *The supply on the market* means any making available of a product for distribution, consumption or use on the market of Republic of Serbia, whether in return for payment or free of charge;

11) *The placing on the market* means the first supply of a product on the market of Republic of Serbia;

12) *The manufacturer* means any entrepreneur or legal person who manufactures a product or has a product designed or manufactured, and places that product on the market under his name or trademark or uses it for his own purposes;

13) *The representative* means any entrepreneur or legal person established within Republic of Serbia who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks prescribed by this Rulebook;

14) T*he importer* means any entrepreneur or legal person established within Republic of Serbia who places on the market a product from another country;

15) *The distributor* means any entrepreneur or the legal person established within Republic of Serbia that is involved in the supply chain, other than the manufacturer or the importer, who supplies a product on the market;

16) *The supplier* means the manufacturer, the representative, the importer and the distributor;

17) *The technical specification* means a document that prescribes technical requirements to be fulfiled by a product;

18) *The harmonised standard* means a European standard adopted on the basis of a request made by the European Commission for the application of European Union harmonised legislation;

19) *The conformity assessment* means the process demonstrating whether a product fulfils the essential health and safety requirements set out in Annex 2 – The essential health and safety requirements relating to the design and construction of equipment and protective systems intended for use in potentially explosive atmospheres, which is printed together with this Rulebook as its integral part;

20) *The conformity assessment body* means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

21) *The recall* means any measure aimed at achieving the return of a product that has already been supplied to the end user;

22) *The withdrawal* means any measure aimed at preventing a product in the supply chain from being supplied on the market;

23) *The European Union harmonised legislation* means any European Union legislation harmonising the conditions for the placing of products on the market;

24) *The conformity marking* means a marking by which the manufacturer indicates that the product is in conformity with the applicable requirements set out in legislation providing for its affixing;

25) *The designated body* means a conformity assessment body notified to the European Commission for the purpose of carrying out conformity assessment tasks in accordance with the legislation referred to in Article 20 of this Rulebook.

Other terms used in this Rulebook, that are not defined in paragraph 1 of this Article, shall have the meanings defined by laws governing technical requirements for products and conformity assessment, market surveillance, standardisation and accreditation.

## II. THE SUPPLY ON THE MARKET AND PUTTING INTO SERVICE

### The Supply on the market and putting into service

### Article 5

The products may be made available on the market and put into service only if, when

properly installed and maintained and used in accordance with their intended use, they comply with this Rulebook.

The specific legislation may prescribe requirements to ensure that people 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 this Rulebook.

Products which do not comply with this Rulebook may be shown at trade fairs, demonstrations, presentations and other similar events, provided that a visible sign clearly indicates that such products do not comply with this Rulebook 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 people.

**The essential health and safety requirements**

**Article 6**

The products shall meet the essential health and safety requirements set out in Annex 2 which apply to them, account being taken of their intended use.

**Marking and labelling of products**

**Article 7**

Manufacturer and importer shall ensure, and distributor shall verify, that each product is supplied on the market and/or put into service bears:

1) The conformity marking and specific marking of explosion protection  , unless the product is a component, and, where applicable, other symbols, markings and information in accordance with Article 13 of this Rulebook;

2) The 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 identification information is provided on the packaging or in a document accompanying the product;

3) The data for identification and contact of the manufacturer and, if applicable, the importer, easily understandable end-users and competent inspectors, i.e.:

− The name and registered trade name or registered trademark of the manufacturer, and the postal address at which they can be contacted or, where the size or nature of the product does not allow it, this information shall be indicated on the product's packaging or in a document accompanying it;

−The name and registered trade name or registered trademark of the importer, and the postal address at which they can be contacted or, where that is not possible, this information

shall be indicated on the product's packaging or in a document accompanying it.

Any labelling of products must be clear, understandable and intelligible.

**The documents accompanying products and technical documentation**

**Article 8**

The manufacturer and importer shall ensure, and distributor shall verify, that each product being supplied on the market and/ or put into service is accompanied by:

1) A copy of the declaration of conformity or, where the product is a component, a copy of the attestation of conformity, unless a large number of products are delivered to a single user, where such consignment may be accompanied by a single copy of the declaration of conformity or attestation of conformity;

2) The instructions and safety information in Serbian language, that shall be clear, understandable and intelligible;

3) Where applicable, a copy of confirmation of conformity in accordance with Article 11 paragraph 6 of this Rulebook.

The manufacturer shall draw up the technical documentation in accordance with appropriate Annexes 3 to 9, depending on the conformity assessment procedure applied in accordance with Article 11 of this Rulebook.

The manufacturer shall keep the declaration of conformity or, where applicable, the attestation of conformity, together with the prescribed technical documentation, for at least 10 years after the product has been placed on the market.

The importer shall keep a copy of the declaration of conformity or, where applicable, a copy of the attestation of conformity, and shall ensure that the technical documentation can be made available to competent market surveillance authorities, for at least 10 years after the product has been placed on the market.

**The free movement**

**Article 9**

The products which comply with requirements of this Rulebook may be supplied on the market and put into service freely, without any restrictions.

## III. THE CONFORMITY OF THE PRODUCT

### The presumption of conformity of products

### Article 10

The product which is in conformity with Serbian standards or parts thereof, transposing the relevant harmonised standards or parts thereof, the list of which (hereinafter referred to as: the list of standards) has been prepared and published in in accordance with the law governing technical requirements for products and conformity assessment shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.

In the absence of harmonised standards, the list of standards may contain references of other Serbian standards or technical specifications regarded as important or relevant to the proper implementation of the essential health and safety requirements set out in Annex 2.

### Conformity assessment procedures

### Article 11

The procedures to be followed for assessing the conformity of equipment and, where necessary, the devices shall be as follows:

1) For equipment of group I category M 1 and equipment of group II category 1, the procedure set out in Annex 3 – Module B: Type examination, which is printed together with this Rulebook as its integral part, in conjunction with one of the following procedures:

(1) The procedure set out in Annex 4 – Module D: Conformity to type based on quality assurance of the production process, which is printed together with this Rulebook as its integral part;

(2) The procedure set out in Annex 5 – Module F: conformity to type based on product verification, which is printed together with this Rulebook as its integral part;

2) For equipment of group I category M 2 and equipment of group II category 2:

(1) In the case of internal combustion motors and electrical equipment, the procedure set out in Annex 3, in conjunction with one of the following procedures:

- The procedure set out in Annex 6 – Module C1: Conformity to type based on internal

production control plus supervised product testing, which is printed together with this Rulebook as its integral part;

- The procedure set out in Annex 7 – Module E: Conformity to type based on product quality assurance, which is printed together with this Rulebook as its integral part;

(2) In case of other equipment, other than internal combustion motor and electrical equipment, the conformity assessment procedure consisting of the procedure set out in Annex 8 – Module A: Internal production control, which is printed together with this Rulebook as its integral part, and the communication of the technical documentation provided for in Annex 8 point 2, to a designated and/or notified body, which shall acknowledge receipt of it as soon as possible and shall retain it;

3) For the equipment of group II category 3, the conformity assessment procedure set out in Annex 8;

4) For the equipment of groups I and II, instead of the procedures referred to in points 1) to 3) of this paragraph, the conformity assessment procedure set out in Annex 9 - Module G: Conformity based on unit verification, which is printed together with this Rulebook as its integral part, may be followed.

The procedure referred to in point 1) or 4) of Paragraph 1 of this Article shall be used for conformity assessment of protective systems.

The conformity assessment procedures referred to in paragraph 1 of this Article shall be applied in respect of components with the exception of the affixing of the conformity marking and the drawing up of the declaration of conformity. For component, a written attestation of conformity shall be drawn up by the manufacturer, declaring the conformity of the component with the applicable requirements of this Rulebook and stating its characteristics and how it must be incorporated into equipment or protective systems to assist compliance with the essential health and safety requirements set out in Annex 2 applicable to finished equipment or protective systems.

For assessment of conformity with regard to the safety aspects referred to in point 1.2.7 of Annex 2, instead of the conformity assessment procedures referred to in Paragraphs 1 and 2 of this Article, the procedure referred to in Annex 8 may be followed.

The manufacturer shall ensure that procedures are in place for series production to remain in conformity with this Rulebook, whereby 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.

Before placing on the market and/or putting into service of equipment referred to in paragraph 1 point 1) and point 2) item (1) of this Article and of protective systems, as well as of devices and components intended for such equipment and protective systems, the conformity of which has been assessed by an appropriate foreign conformity assessment body, the manufacturer, his representative, the importer or the person importing a product in order to use it for his own purposes, shall obtain document of conformity referred to in Annex 13 – Confirmation of conformity, which is printed together with this Rulebook as its integral part.

**The Declaration of conformity**

**Article 12**

The declaration of conformity shall state that the fulfilment of the essential health and safety requirements set out in Annex 2 has been demonstrated.

The declaration of conformity shall be drawn up in Serbian language, or it shall be ensured that it is translated into Serbian language, in accordance with the model set out in Annex 10 – The model of the declaration of conformity, which is printed together with this Rulebook as its integral part, so that it contains the elements specified in the relevant conformity assessment procedures set out in Annexes 3 to 9, and shall be continuously updated.

Where a product is the subject to more than one legislation requiring a declaration of conformity, a single declaration of conformity shall be drawn up in respect of all such legislation, containing the identification of all such legislation, whereby a dossier made up of relevant individual declarations of conformity shall also be considered as such single declaration of conformity.

By drawing up the declaration of conformity, the manufacturer shall assume responsibility for the compliance of the product with the requirements laid down in this Rulebook.

**The conformity marking**

**Article 13**

The conformity marking set out in Annex 12 – The conformity marking, which is printed together with this Rulebook as its integral part, shall be affixed to the product, other

than component, which complies with the requirements of this Rulebook, before the product is placed on the market.

The conformity marking shall be subject to the general principles set out in the law governing technical requirements for products and conformity assessment and specific legislation adopted pursuant to provisions of that law.

The conformity marking shall be affixed to the product or its data plate so that it is visible, legible and indelible or, where that is not possible or not warranted on account of the nature of the product, it shall be affixed to the packaging or to the accompanying documents.

The conformity marking shall be followed by the unique identification number of the designated body, where that body is involved in the production control phase of the conformity assessment.

The conformity marking and, where applicable, the unique identification number of the designated 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 Annex 2.

The conformity marking, the markings, symbols and information referred to in Paragraph 5 of this Article, and, where applicable, the unique identification number of the designated 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.

## IV. THE DESIGNATED CONFORMITY ASSESSMENT BODY

### The requirements for carrying out conformity assessment

### Article 14

A conformity assessment body may carry out conformity assessment, in accordance with Annexes 3 to 7, 9 and 13, if it meets the requirements set out in Annex 11 – Requirements that must be met by a conformity assessment body in order to be designated for conformity assessment, which is printed together with this Rulebook as its integral part, and if it is designated in accordance with the law governing technical requirements for products and conformity assessment and specific legislation adopted pursuant to provisions of that law (hereinafter referred to as: The designated body).

### The presumption of conformity with requirements for the designated body

### Article 15

Where a conformity assessment body demonstrates compliance with the requirements laid down in the relevant Serbian standards or parts thereof, it shall be presumed to comply with requirements set out in Annex 11 of this Rulebook, insofar as such standards cover those requirements. Relevant Serbian standards referred to in this Article are the Serbian standards transposing the relevant harmonised standards which contain requirements for conformity assessment bodies.

**The requirements for designated body in relation to subcontracting**

**Article 16**

Where the designated body, with the agreement of the client, entrusts a subcontractor, including a subsidiary, in the country or abroad, with specific tasks connected with conformity assessment, for which it has been designated, the designated body shall ensure that such subcontractor meets the requirements set out in Annex 11 of this Rulebook and it shall keep the proof of it and make it available to the designation authority in accordance with the law governing technical requirements for products and conformity assessment. The Designated body which entrusts a subcontractor with specific tasks connected with conformity assessment shall take full responsibility for the performance of such entrusted tasks.

## V. THE REQUIREMENTS FOR THE SAFETY OF PRODUCT AFTER THE SUPPLY ON THE MARKET OR IN USE AND THE SAFEGUARD CLAUSE

**The requirements for the safety of product after the supply on the market**

**Article 17**

A supplier shall keep and make available to the competent authorities the information necessary to identify any supplier who has supplied him with a product or to whom he has supplied a product, for at least 10 years after the supply of a product.

A supplier shall ensure that the competent authorities are provided with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of a product with the requirements of this Rulebook, in accordance with the law governing technical requirements for products and conformity assessment.

When it is appropriate with a regard to the risks presented by the product, the manufacturer shall, to protect the health and safety of end-users, ensure that sample testing of

products made available on the market is carried out, 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, in accordance with the law governing technical requirements for products and conformity assessment.

If he considers or has reason to believe that a product which he has placed on the market is not in conformity with this Rulebook, the manufacturer and/ or the importer shall take the corrective measures, and the distributor shall ensure that they are taken, necessary to bring that product into conformity, to withdraw it or recall it, if appropriate, in accordance with the law governing technical requirements for products and conformity assessment. Where the product presents a risk to the health and safety of people or domestic animals, or to property, he shall immediately inform the competent market surveillance authority to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

The supplier shall ensure that corrective action is taken in respect of all the products concerned that he has supplied on the market.

Where the relevant economic operator does not take adequate corrective action referred to in paragraphs 4 and 5 of this Article, appropriate measures shall be taken in accordance with the law governing technical requirements for products and conformity assessment.

**Formal non-compliance**

**Article 18**

Where one of the following findings is made, the product shall be regarded as formally non-compliant:

1) The conformity marking has been affixed in violation of Article 13 of this Rulebook;

2) If applicable, the conformity marking has not been affixed;

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

4) The unique identification number of the Designated body, where that body is involved in the production control phase, has been affixed in violation of Article 13 of this Rulebook or has not been affixed;

5) The declaration of conformity or, where applicable, the attestation of conformity, does not

accompany the product;

6) The declaration of conformity has been drawn up in violation of Article 12 of this Rulebook or, where applicable, the attestation of conformity has been drawn up in violation of Article 11 paragraph 3 of this Rulebook;

7) The technical documentation is either not available or not complete;

8) The information referred to in Article 7 paragraph 1 point 3) of this Rulebook is absent, false or incomplete;

9) Any other requirement of this Rulebook not specified in points 1)-8) of this paragraph is not fulfiled, other than health and safety requirements set out in Annex 2.

Where the formal non-compliance referred to in paragraph 1 of this Article is not dealt with, appropriate measures shall be taken in accordance with the law governing technical requirements for products and conformity assessment.

**The safeguard clause regarding the compliant products which present a risk**

**Article 19**

The supply or use of a product in compliance with the requirements of this Rulebook may be restricted or forbidden in accordance with the law governing technical requirements for products and conformity assessment, where it is found that such product presents a risk to the health or safety of people or to domestic animals or property.

## VI. THE ALIGNMENT TO EUROPEAN UNION LEGISLATION

**Article 20**

This Rulebook is aligned to the 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.

## VII. THE TRANSITIONAL AND FINAL PROVISIONS

**Article 21**

From the date of entry into force of a ratified international agreement on conformity assessment and acceptance of industrial products with the European Union (hereinafter: the ACAA Agreement) for products covered by this Rulebook or, if such agreement is not concluded, from the date of Republic of Serbia's accession to the European Union, in all provisions and titles within this Rulebook where they are used, the words: " the declaration of conformity" shall be construed as: "EU declaration of conformity", words: "the conformity marking" shall be construed as: "CE marking", words: "the type examination" shall be construed as: "the EU type examination", words: "the type examination certificate" shall be construed as: "the EU type examination certificate", word: "designated" shall be construed as: "notified", word: "designation" shall be construed as: "notification", in the used case and number, and in Article 13 paragraph 1 words: " The conformity marking set out in Annex 12 – Conformity marking, which is printed together with this Rulebook as its integral part" shall be construed as: "CE marking".

From the date of Republic of Serbia's accession to the European Union, or in accordance with the provisions of the agreement on Republic of Serbia's accession to the European Union, in Article 4 paragraph 1 points 10) to 15) of this Rulebook, words: "The Republic of Serbia", in the used case, shall be construed as "The European Union", in the same case in Article 4 paragraph 1 point 14) words: "from another country" shall be construed as: "from the third countries", in Article 8 paragraph 1 point 2) words: "in Serbian language" shall be construed as: "in a language easily understood by end-users and market surveillance authorities", and in Article 13 paragraph 2 words: "the law governing technical requirements for products and conformity assessment and specific legislation adopted pursuant to provisions of that law" shall be construed as: "Article 30 of Regulation (EC) No 765/2008", and in point 5 of Annex 10 words: "the relevant legislation" shall be construed as: "the relevant European Union harmonised legislation".

**Article 22**

From the date of entry into application of this Rulebook until the date of entry into force of the ACAA Agreement for products covered by this Rulebook or, if such agreement is not concluded, until the date of Republic of Serbia's accession to the European Union, the marking of conformity of electrical equipment shall be carried out by affixing the Serbian conformity marking in accordance with this Rulebook and specific legislation.

From the date of entry into force of the ACAA for the electrical equipment covered by this Rulebook or, if such agreement is not concluded, from the date of Republic of Serbia's

accession to the European Union, or in accordance with the provisions of the agreement on Republic of Serbia's accession to the European Union, the marking of conformity shall be carried out by affixing the CE marking in accordance with this Rulebook and specific legislation.

**Article 23**

With the effect from the date of entry into force of the ACAA Agreement for products covered by this Rulebook or, if such agreement is not concluded, from the date of Republic of Serbia's accession to the European Union, or in accordance with the provisions of the agreement on Republic of Serbia's accession to the European Union, the provisions of Article 12 paragraph 2 cease to be applied.

**Article 24**

With the effect from the date of entry into application of this Rulebook, the Rulebook on equipment and protective systems intended for use in potentially explosive atmospheres ("Official Gazette of RS", No 1/13) is repealed.

The certificates which were issued, before entry into application of this Rulebook, by the conformity assessment bodies designated in accordance with the legislation referred to in paragraph 1 of this Article, shall remain valid until the date of expiration.

The conformity assessment bodies referred to in paragraph 2 of this Article may submit their applications for designation in accordance with this Rulebook to the competent designating authority within the period of 6 months after the date of its entry into application.

The conformity assessment bodies referred to in paragraph 2 of this Article may, from the date of entry into application of this Rulebook until the completion of designation procedure in accordance with this Rulebook, carry out conformity assessment tasks set out in Article 11 of this Rulebook and in accordance with Annexes from 3 to 7 and 9, on the basis of valid decision on designation, as well the tasks in accordance with Annex 13.

Where the conformity assessment bodies referred to in paragraph 2 of this Article do not submit their applications for designation within the period referred to in paragraph 3 of this Article and/ or where the designating authority, after submission of those applications, determines that they do not comply with the requirements of this Rulebook, they shall not be able to carry out the conformity assessment as Designated bodies in accordance with this Rulebook.

**Article 25**

This Rulebook shall enter into force on the eighth day from the date of its publication in the „Official Gazette of the Republic of Serbia”, and shall start to apply on 1 May 2017.

**The independent members of the Rulebook on changes of the Rulebook on the equipment and protective systems intended for use in potentially explosive atmospheres**

("Official Gazette of RS", No. 21/2020)

**Article 3**

The provisions of Article 8, paragraph 1, point 3 and Article 11, paragraph 6 and Annex 13 of the Certificate of Conformity, Rulebook on equipment and protective systems intended for use in potentially explosive atmospheres ("Official Gazette of RS", No. 10/17) , cease to be valid on 1 January, 2023.

**Article 4**

This Rulebook shall enter into force on the eighth day from the day of its publication in the "Official Gazette of the Republic of Serbia".

**ANNEX 1**

**THE CRITERIA DETERMINING THE CLASSIFICATION OF EQUIPMENT-GROUPS INTO CATEGORIES**

1. **The equipment-group I**

(a) The 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.

The 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.

The equipment category M 1 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.

The equipment category M 1 must comply with the supplementary requirements referred to in point 2.0.1 of Annex II.

(b) The 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.

The equipment in this category is intended for use in the 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.

In the event of an explosive atmosphere, it must be possible to disconnect this equipment from the power source.

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.

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

**2. The equipment-group II**

(a) The 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.

The 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.

The equipment of category 1 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.

The equipment of category 1 must comply with the supplementary requirements referred to in point 2.1 of Annex II.

(b) The 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.

The 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.

The equipment in this category must comply with the supplementary requirements referred to in point 2.2 of Annex II.

(c) The 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.

The 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.

The equipment in this category ensures the requisite level of protection during normal operation. The equipment of category 3 must comply with the supplementary requirements referred to in point 2.3 of Annex II.

## ANNEX 2

## THE 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. When designing and manufacturing the products referred to in Article 2 of this Rulebook, the latest technological knowledge must be taken into account, as far as possible, and

applied immediately.

B. The essential health and safety requirements apply to the devices referred to in Article 2, point 2 of this Rulebook only to the extent necessary for the safe and reliable operation and operation of those devices in relation to the risks of explosion.

**1. The Common requirements for the equipment and protective systems**

1.0. *The General requirements*

1.0.1. The principles of integrated explosive safety

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

The principle of integrated explosion safety means that the manufacturer must undertake the following measures:

- 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,
- If an explosion occurs, which could directly or indirectly endanger people, and, where applicable, domestic animals or property, stop it immediately and / or limit the range of flames and pressure of the explosion to a sufficient level of safety.

1.0.2. The prevention of dangerous situations and potential misuse

The 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. The special inspection and maintenance conditions

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

1.0.4. The surrounding area conditions

The 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. The marking

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

- The name, the registered trade name or the registered trademark, and the address of the manufacturer,
- The conformity marking,
- The designation of series or type,
- The batch or serial number, if any,
- The year of construction,
- The specific marking of explosion protection followed by the symbol of the equipment-group and category,
- For the 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).

In addition to the information referred to in paragraph 1 of this item, where necessary, the equipment and protective systems must be marked with all information relevant to their safe use.

1.0.6. The instructions

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

1) A summary of the information which the equipment or protective system is marked with, except for the batch or serial number (see point 1.0.5 of this Annex), with the appropriate additional information for maintenance purposes (e.g. service address, etc.);

2) The instructions for safe:

- putting into service,
- use,
- assembling and dismantling,
- maintenance (servicing and emergency repair),
- installation,
- adjustment;

3) Where necessary, an indication of the danger areas in front of pressure-relief devices;

4) Where necessary, training instructions;
5) The 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;
6) The electrical and pressure parameters, maximum surface temperatures and other limit values;
7) Where necessary, the special conditions of use, including the particulars of the possible misuse which experience has shown might occur;
8) Where necessary, the essential characteristics of tools which may be fitted to the equipment or protective system.

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.

The documentation 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. The 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. *The design and construction*

1.2.1. The 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. The components to be incorporated into or used as replacements in equipment and protective systems must be designed and constructed so 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 so that the releases of gases or dusts cannot give rise to explosive atmospheres outside the equipment.

The 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. The dust deposits*

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

In general, dust deposits must be limited where possible. The 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. The additional means of protection*

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

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

*1.2.6. The safe opening*

If equipment and protective systems are in the housing or the 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. The protection against other hazards*

The equipment and protective systems must be designed and manufactured so 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 known by experience;

(d) Assure that foreseeable conditions of overload do not give rise to dangerous situations.

Where, for the equipment and protective systems, the risks referred to in this subsection are wholly or partly covered by other regulations, which ensure harmonisation with the harmonised legislation of the European Union, on those risks these other regulations shall apply.

*1.2.8. The overloading equipment*

The 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, over speed monitors and/ or similar types of monitoring devices.

*1.2.9. Flameproof enclosure items*

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 the 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. The 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.. The hazards arising from static electricity*

The electrostatic charges capable of resulting in dangerous discharges must be prevented by the means of appropriate measures.

*1.3.3. The hazards arising from stray electric and leakage currents*

The 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. The 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. The hazard arising from pressure compensation operations*

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

*1.4. The hazards arising from the external effects*

1.4.1. The equipment and protective systems must be designed and constructed so 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. The 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. The requirements in respect of safety-related devices*

1.5.1. The 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 the 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.

The 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 be, wherever possible, secured.

1.5.3. The 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. The control and display units (displays)

When 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. The requirements in respect of devices with measuring function for explosion protection

As far as these devices relate to equipment used in explosive atmospheres, the devices with

the 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. The risks arising from software*

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

1.6. The *integration of safety requirements relating to the system*

1.6.1. The 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. The 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 the safe state of operation independently of the rest of the installation.

*1.6.4. The hazards arising from connections*

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

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

*1.6.5. The installation of warning devices as 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. *The requirements applicable to equipment in equipment-group I*

2.0.1. The requirements applicable to equipment category M 1 equipment - group I

2.0.1.1. The 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.

The 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, the equipment must be equipped with additional special means of protection. It must remain functional with the explosive atmosphere present.

2.0.1.2. Where necessary, the equipment must be constructed so 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. The equipment must be designed so 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, the equipment must be fitted with appropriate additional interlocking systems.

*2.0.2. The requirements applicable to equipment category M 2 - g r o u p I*

2.0.2.1. The 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.

In the event of an explosive atmosphere, it must be possible to disconnect this equipment from the power supply.

2.0.2.2. The equipment must be designed so 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. *The requirements applicable to equipment category 1 of equipment-group II*

2.1.1. Explosive atmospheres used by gases, vapours or mists

2.1.1.1. The equipment must be designed and constructed so 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 from each other.

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

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

2.1.1.3. The equipment must be designed so 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, the equipment must be fitted with the appropriate additional interlocking systems.

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

2.1.2.1. The equipment must be designed and constructed so 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, the equipment must be designed so 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 a regard to the safe opening of equipment parts, requirement 2.1.1.3 applies.

2.2. *The requirements applicable to equipment category 2-group II*

*2.2.1. Explosive atmospheres used by gases, vapour or mists*

2.2.1.1. The 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. The equipment parts must be designed and constructed so 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. The equipment must be designed so 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 used 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. *The requirements applicable to equipment category 3-group II*

*2.3.1. Explosive atmospheres used by gases, vapours or mists*

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

2.3.1.2. The 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 used by air / dust mixtures*

2.3.2.1. The 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 a regard to the surface temperatures, requirement 2.1.2.3 applies.

2.3.2.3. The equipment, including cable entries and connecting pieces, must be constructed so 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. The 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. The protective systems must be designed and capable of being positioned in such a way so that the explosions are prevented from spreading through dangerous chain reactions or flashovers and incipient explosions do not become detonations.

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

3.0.4. The protective systems must not fail due to outside interference.

3.1. *The planning and design*

3.1.1. Characteristics of the materials

With a 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. The protective systems designed to resist or contain explosions must be capable of withstanding the shock wave produced without losing system integrity.

3.1.3. The 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 people in the vicinity.

3.1.6. Explosion suppression systems

Explosion suppression systems must be planned and designed so 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. The 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 3

## MODULE B: TYPE EXAMINATION

1. The type examination is the part of a conformity assessment procedure in which a Designated body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of this Rulebook that apply to it.

2. The type examination is carried out with the examination of a specimen, representative of the production envisaged, of the complete product (production type).

3. The manufacturer makes a request for type examination with a single Designated body of his choice.

The request must include:

(1) The name and address of the manufacturer and, if the request is made by the authorised representative, his name and address as well,

(2) The written statement that the same request has not been made with any other Designated body,

(3) The technical documentation. The technical documentation shall make it possible to assess the products' conformity with the applicable requirements of this Rulebook 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) The general description of the product,

(ii) The conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.

(iii) The descriptions and explanations necessary for 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 and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Rulebook, 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) The results of design calculations made, examinations carried out, etc.,
and

(vi) The test reports,

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

4. The Designated 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, have been applied correctly;

4.3. Carry out the 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 Rulebook;

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

5. The Designated 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 towards the competent authorities, the Designated 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 Rulebook that apply to the product concerned, the Designated body shall issue a type examination certificate to the manufacturer. That certificate contains 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 Type Examination Certificate may have one or more annexes attached.

The Type Examination Certificate and its annexes must 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 Rulebook, the Designated body shall refuse to issue a Type Examination Certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The Designated body shall keep itself informed 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 Rulebook, and shall determine whether such changes require further investigation. If so, the Designated body shall inform the manufacturer accordingly.

The manufacturer shall inform the Designated body that holds the technical documentation relating to the 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 Rulebook or the conditions for validity of that certificate. Such modifications require additional approval in the form of an addition to the original Type Examination Certificate.

8. The Designated body must inform the competent authority concerning the Type Examination Certificates and/ or any additions thereto to which it has issued or withdrawn, and shall, periodically or upon request, make available to the competent authority the list of such certificates and/ or any additions thereto refused, suspended or otherwise restricted.

The Designated body must inform the other Designated bodies concerning the 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 Designated body, on the request of the competent authorities and other designated bodies provides copies of the Type Examination Certificates and/ or additions thereto. At the request of the competent authorities, the Designated body also supplies copies of the technical documentation and the results of the examinations carried out by the Designated body. The Designated body must keep a copy of the 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 must keep a copy of the 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 was placed on the market.

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

## ANNEX 4

## MODULE D: CONFORMITY TO TYPE BASED ON PRODUCTION QUALITY ASSURANCE

1. Conformity to type based on production quality assurance 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 Type Examination Certificate and satisfy the requirements of this Rulebook that apply to them.

2. **Manufacturing**

The manufacturer must 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. **The quality system**

3.1. The manufacturer shall make a request for assessment of his quality system with the Designated body of his choice, for the products concerned.

The request must include:

(a)The name and address of the manufacturer and, if the request is made by the authorised representative, his name and address as well,

(b) The written statement that the same request was not made with any other Designated 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 Type Examination Certificate.

3.2. The quality system shall ensure that the products are in conformity with the type described in the type examination certificate and comply with the requirements of this Rulebook that apply to them.

All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

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

It must, 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 which they will be carried out with,

(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 Designated body assesses the quality system in order 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 the experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of this Rulebook.

The audit includes an assessment visit to the manufacturer’s premises. The auditing makes a review on the technical documentation referred to in point 3.1(e) to verify the manufacturer’s

ability to identify the relevant requirements of this Rulebook and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision must be notified to the manufacturer. The notification must 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 Designated body that has approved the quality system informed of any intended change to the quality system.

The Designated body evaluates any proposed changes and decides whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It notifies the manufacturer of its decision. The notification must contain the conclusions of the examination and the reasoned assessment decision.

**4. Surveillance under the responsibility of the Designated 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 Designated body the access to the manufacture, inspection, testing and storage sites and provides 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 Designated 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. The Designated body may pay unexpected visits to the manufacturer during such visits the Designated body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system functions correctly. The Designated body shall provide the manufacturer with a Visit Report and, if tests were carried out, with a Test Report.

**5. Conformity marking, declaration of conformity and attestation of conformity**

5.1. The manufacturer shall affix the conformity marking and, under the responsibility of the Designated body referred to in point 3.1. of this Annex, the identification number of that

body, on each individual product, unless it is a component, which conforms to the type described in the Type Examination Certificate and which meets the applicable requirements of this Rulebook.

5.2. The manufacturer draws up a declaration of conformity for each product model, other than a component and keeps it at the disposal of the competent authorities at least for 10 years after the product other than a component was placed on the market. The declaration of conformity states a product model for which it was drawn up.

A copy of the declaration of conformity accompanies every product, other than a component.

5.3. The manufacturer draws up the attestation of conformity for each component model and keeps it at the disposal of the competent authorities at least for 10 years after the component was placed on the market. The attestation of conformity also states the component model for which it was drawn up. A copy of the attestation of conformity accompanies every component.

6. The manufacturer, at least for 10 years after the component was placed on the market, keeps at the disposal of the competent 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 Designated body referred to in points 3.5, 4.3 and 4.4.

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

The Designated body must inform the other Designated bodies of quality system approvals which it refused, suspended, withdrew or otherwise restricted, and, upon request, of quality system approvals which it issued.

**8. The authorised representative**

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

## ANNEX 5

## 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, 5 and 6 of this Annex and ensures and declares on his sole responsibility that the products concerned, which were the subject to the provisions of point 3, are in conformity with the type described in the Type Examination Certificate and satisfy the requirements of this Rulebook that apply to them.

**2. Manufacturing**

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

**3. Verification**

A Designated body chosen by the manufacturer carries out appropriate examinations and tests in order to check the conformity of the products with the approved type described in the Type Examination Certificate and with the appropriate requirements of this Rulebook.

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

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

4.1. Each product must 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, must be carried out in order to verify conformity with the approved type described in the Type Examination Certificate and with the appropriate requirements of this Rulebook.

In the absence of such harmonised standards, the Designated body concerned decides on the appropriate tests to be carried out.

4.2. The Designated body issues a certificate of conformity in respect of the tests which were carried out, and affixes its identification number to each approved product or has it affixed under its responsibility.

The manufacturer must keep the certificates of conformity available for inspection by the competent authorities at least for 10 years after the product was placed on the market.

**5. Conformity marking, declaration of conformity and attestation of conformity**

5.1. The manufacturer affixes the conformity mark and, under the responsibility of the Designated body referred to in point 3 of this Annex identification number of that body to each individual product other than a component that is in conformity with the approved type described in the Type Examination Certificate and satisfies the applicable requirements of this Rulebook.

5.2. The manufacturer draws up a declaration of conformity for each product model, other than a component and keeps it at the disposal of the competent authorities at least for 10 years after the product other than a component was placed on the market. The declaration of conformity states a product model for which it was drawn up.

A copy of the declaration of conformity accompanies every product, other than a component.

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

5.3. The manufacturer draws up the attestation of conformity for each component model and keeps it at the disposal of the competent authorities at least for 10 years after the component was placed on the market. The attestation of conformity also states the component model for which it was drawn up. A copy of the attestation of conformity accompanies every component.

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

7. **The authorised representative**

The manufacturer's obligations may be fulfiled by his authorised representative, on his behalf and under his responsibility, provided that it was defined by the authority which the manufacturer gave to his representative.

## ANNEX 6

## 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 Type Examination Certificate and satisfy the requirements of this Rulebook that apply to them.

**2. Manufacturing**

The manufacturer takes all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the type described in the Type Examination Certificate and with the requirements of this Rulebook that apply to them.

**3. The 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 Type Examination Certificate and with the corresponding requirements of this Rulebook. The tests are carried out under the responsibility of a Designated body, chosen by the manufacturer.

The manufacturer, under the responsibility of the Designated body, affixes the designated body's identification number during the manufacturing process.

4. **Conformity marking, declaration of conformity and attestation of conformity**

4.1. The manufacturer affixes the conformity mark to each individual product other than a component that is in conformity with the type described in the Type Examination Certificate and satisfies the applicable requirements of this Rulebook.

4.2. The manufacturer draws up a declaration of conformity for each product model, other than a component and keeps it at the disposal of the competent authorities at least for 10 years after the product other than a component was placed on the market. The declaration of conformity states a product model for which it was drawn up.

A copy of the declaration of conformity accompanies every product, other than a component.

4.3. The manufacturer draws up the attestation of conformity for each component model and keeps it at the disposal of the competent authorities at least for 10 years after the component was placed on the market. The attestation of conformity also states the component model for which it was drawn up. A copy of the attestation of conformity accompanies every

component.

**5. The authorised representative**

The manufacturer's obligations set out in point 4 may be fulfiled by his authorised representative, on his behalf and under his responsibility, provided that it was defined by the authority which the manufacturer gave to his representative.

## ANNEX 7

## 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 Type Examination Certificate and satisfy the requirements of this Rulebook that apply to them.

**2. Manufacturing**

The manufacturer must have 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. The quality system**

3.1. The manufacturer makes a request for assessment of his quality system with the Designated body of his choice, for the products concerned.

The request must include:

(a) The name and the address of the manufacturer and, if the request is made by the authorised representative, his/ her name and address as well,

(b) The written statement that the same request has not been made with any other Designated 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 Type Examination Certificate.

3.2. The quality system shall ensure compliance of the products with the type described in the Type Examination Certificate and with the applicable requirements of this Rulebook.

All the elements, requirements and provisions adopted by the manufacturer are documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

The quality system documentation must permit a consistent interpretation of 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 Designated 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 Rulebook. 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 Rulebook and to carry out the necessary examinations with a view to ensuring compliance of the product with those requirements.

The decision shall be designated 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 Designated body that has approved the quality system

informed of any intended change to the quality system.

The Designated 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 Designated 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 Designated 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 Designated 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. The Designated body may pay unexpected visits to the manufacturer. During such visits the Designated 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 Designated body shall provide the manufacturer with a Visit Report and, if tests have been carried out, with a Test Report.

**5. Conformity marking, declaration of conformity and attestation of conformity**

5.1. The manufacturer shall affix the conformity mark and, under the responsibility of the Designated 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 Type Examination Certificate and satisfies the applicable requirements of this Rulebook.

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

A copy of the 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 competent authorities at least 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 at least 10 years after the product was placed on the market, keep at the disposal of the competent 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 Designated body referred to in points 3.5, 4.3 and 4.4.

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

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

8. **The authorised representative**

The manufacturer's obligations set out in point points 3.1, 3.5, 5 and 6 may be fulfiled by his authorised representative, on his behalf and under his responsibility, provided that it was defined by the authority which the manufacturer gave to his representative.

## ANNEX 8

## 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 Rulebook that apply to them.

2. **The 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) The general description of the product,

(b) The conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.

(c) The 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 and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Rulebook, 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) The 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 Rulebook that apply to them.

4. **The conformity marking, declaration of conformity and attestation of conformity**

4.1. The manufacturer shall affix the conformity mark to each individual product other than a component that satisfies the applicable requirements of this Rulebook.

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

A copy of the 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 at least 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 accompanies every component.

5. The **authorised representative**

The manufacturer's obligations set out in point points 4 may be fulfiled by his authorised representative, on his behalf and under his responsibility, provided that it was defined by the authority which the manufacturer gave to his representative.

## ANNEX 9

## 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 Rulebook that apply to it.

2. **The technical documentation**

2.1. The manufacturer shall establish the technical documentation and make it available to the Designated 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) The general description of the product,

(b) The conceptual design and manufacturing drawings and schemes of components, subassemblies, circuits, etc.

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

(d) The list of the harmonised standards applied in full or in part and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Rulebook, 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)The results of design calculations made, examinations carried out, etc.,

and

(f) The test reports.

2.2. The manufacturer shall keep the technical documentation at the disposal of the competent authorities for at least 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 Rulebook.

4. **Verification**

A Designated 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 Rulebook, or have them carried out. In the absence of such a harmonised standard the Designated body concerned shall decide on the appropriate tests to be carried out. The Designated 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 competent authorities for at least 10 years after the product was placed on the market.

5. **Conformity marking, declaration of conformity and attestation of conformity**

5.1. The manufacturer affixes the conformity mark and, under the responsibility of the Designated 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 Rulebook.

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

A copy of the 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 competent authorities at least 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. **The authorised representative**

The manufacturer's obligations set out in points 2.2 and 5 may be fulfiled by his authorised representative, on his behalf and under his responsibility, provided that it was defined by the authority which the manufacturer gave to his representative.

## ANNEX 10
## MODEL OF DECLARATION OF CONFORMITY

The declaration of conformity is made according to the following model, where it is not necessary to state the number of the declaration in the title:

**DECLARATION OF CONFORMITY (No XXXX)**

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

2. The 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 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 designated 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 11

## REQUIREMENTS TO BE FULFILED BY THE CONFORMITY ASSESSMENT BODY TO BE DESIGNED FOR CONFORMITY ASSESSMENT

1. For the purposes of designation, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. A conformity assessment body shall be registered in RS and shall 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 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.

A conformity assessment body, its 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 designated. This shall in particular apply to consultancy services.

Conformity assessment bodies must 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 conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes III to VII and Annex IX and in relation to which it has been designated, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

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

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

(b) The 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 the Designated body and other activities;

(c) The 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.

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) The sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been designated;

(b) The satisfactory knowledge of the requirements of the assessments they carry out and

adequate authority to carry out those assessments;

(c) The appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, of the relevant provisions of this Rulebook and other regulations that ensure the conformity of national legislation with the regulation referred to in Article 20 of this Rulebook;

(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 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. The conformity assessment bodies shall take out liability insurance.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks, except in relation to the competent authorities of the RS. Proprietary rights shall be protected.

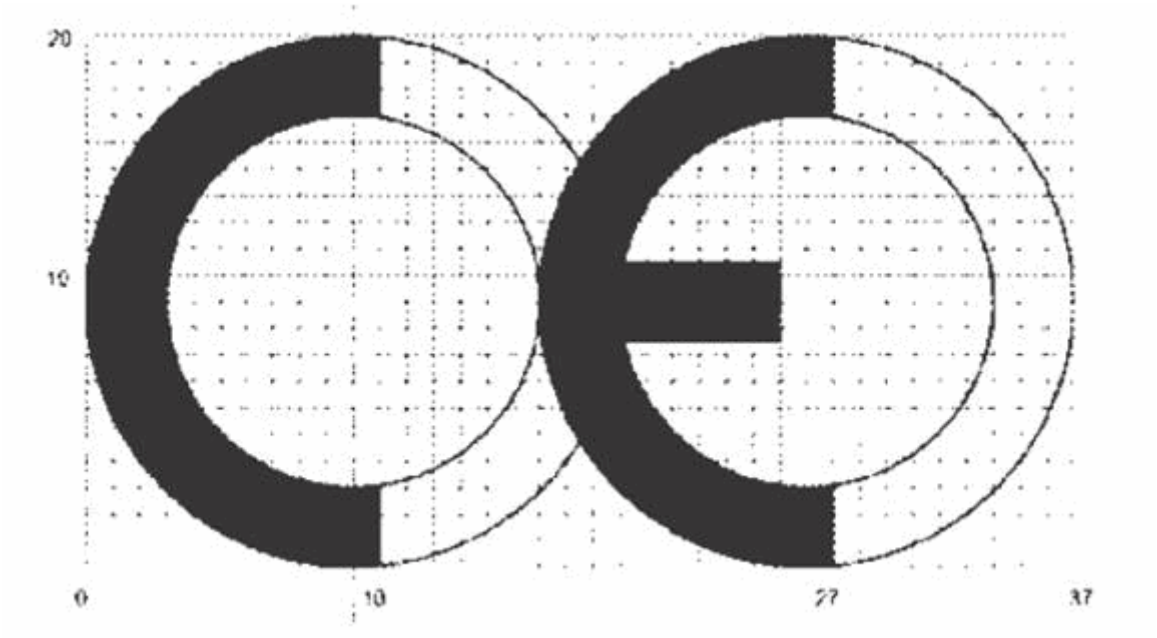
11. The conformity assessment body must participate in the relevant activities of standardization organisations and group activities established with the aim of ensuring coordination of the Designated bodies, that is to ensure that its staff conducting conformity assessment activities are familiar with the activities of those organizations and groups. As a rule, the Designated body applies as general guidelines the decisions and documents of the group for coordination of the Designated bodies, in order to perform consistent and equally high-quality work and conduct conformity assessment activities.

## ANNEX 12

## CONFORMITY MARK

### 1. CE MARKING

CE mark has the following appearance and shape:




Height of the CE mark may not be less than 5 mm.

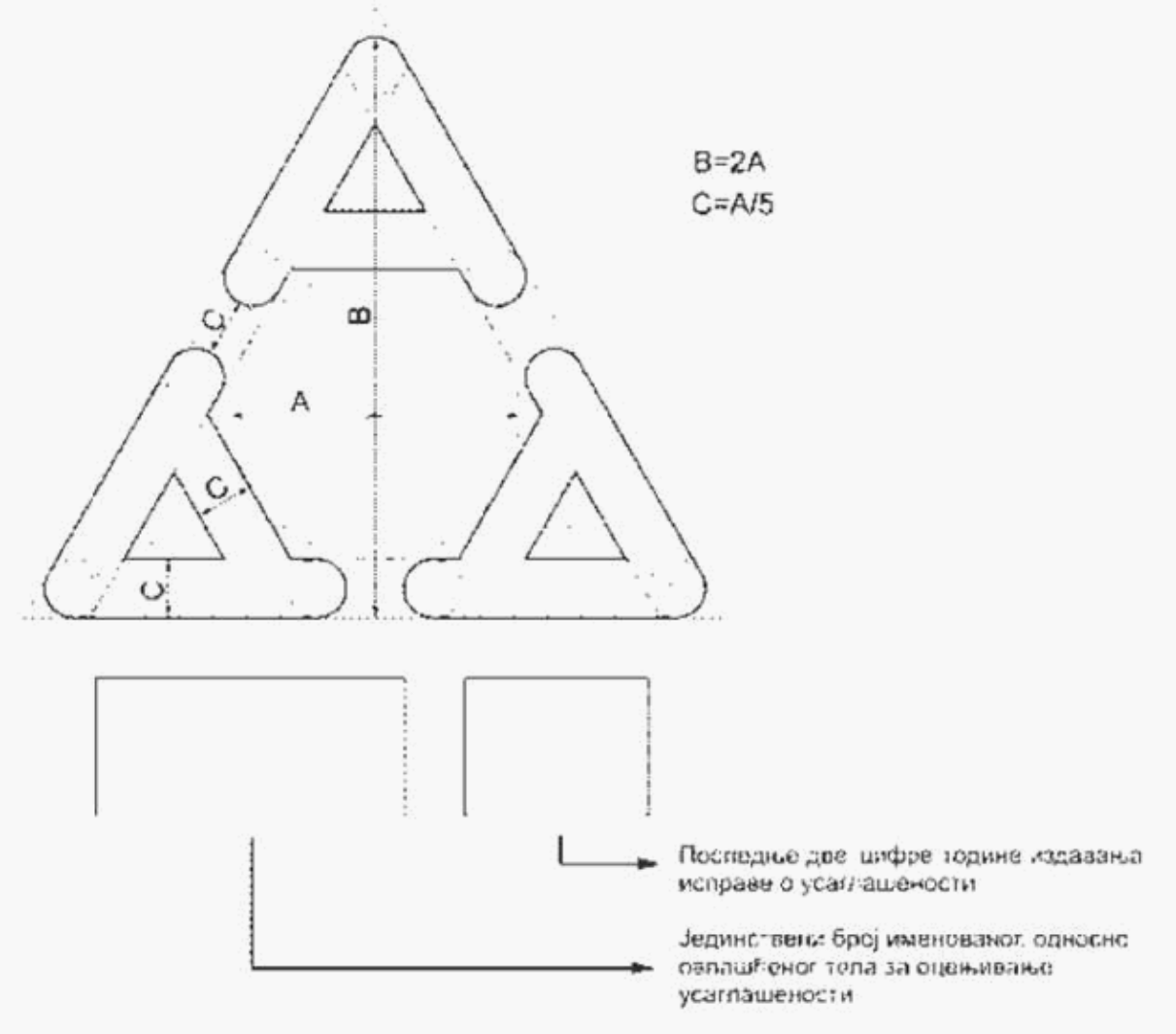
If the CE mark is reduced or enlarged the proportions shown in the above drawing must be respected.

The minimum dimension may be waived for small-scale equipment.

CE mark must be followed by the identification number of the Designated body which participated in the assessment of conformity in the production control phase.

**2. THE SERBIAN CONFORMITY MARK**

The Serbian conformity mark consists of three capital letters “A” interconnected in the shape of an equilateral triangle (3A), of appearance and contents as in the figure below:




Size of the mark shall be determined by the height B of the mark which may only have values of standard numbers rounded up, to the order of magnitude R10 expressed in millimeters (mm), as per Serbian standard – Standard numbers, numerical values and definitions – SRPS A.A0.001.

The height B of the mark shall be, as a rule, at least 5 millimetres.

The identification number of the Designated body from the Registry of the Designated bodies for conformity assessment, and the last two digits of the year of issue of the conformity document, if this body performed, or participated in, conformity assessment, must be placed next to the Serbian mark.

## ANNEX 13

## THE CONFIRMATION OF CONFORMITY

1. The confirmation of conformity is a document of conformity which is issued by a Designated body on the basis of the procedure set out in point 3. of this Annex, to confirm

that the product is in conformity with the requirements of this Rulebook that apply to it.

2. The manufacturer, the representative or the importer, or the person importing a product to use it for his own purposes makes a request for verification of conformity to a Designated body of his choice.

The request for carrying out the procedure set out in point 3.2. of this Annex may be made only by the manufacturer or his representative, or by the importer authorised by the manufacturer.

The application shall include:

− The name and address of the manufacturer;

− The name and address of the applicant, if the application is not lodged by the manufacturer;

−The identification of the procedure referred to in point 3. of this Annex, for carrying out of which the application is being lodged;

− Where applicable, a written authorisation of the manufacturer to the representative or the importer for carrying out the procedure referred to in point 3.2 of this Annex;

− a written declaration that the same application has not been made with any other Designated body;

− The copy(ies) of relevant certificate(s) issued by foreign conformity assessment body(ies), in accordance with the conformity assessment scheme set out in Article 11 of this Rulebook, i.e. in accordance with appropriate modules set out in Annexes 3 to 7 and 9. Where the request is being made for carrying out of the procedure referred to in point 3.2. of this Annex, the certificates shall cover both stages (or modules) of the conformity assessment procedure;

− The instructions and safety information drawn up by the manufacturer;

− The other documents, where it is necessary for carrying out the procedure referred to in point 3. of this Annex and/or for drawing up the confirmation of conformity referred to in point 4.4. of this Annex.

**3. The confirmation of conformity procedure**

The Designated body shall review the application and examine and assess the included documents to determine whether the confirmation of conformity can be carried out in accordance with the requested procedure. The confirmation of conformity procedure on the basis of a foreign document of conformity, which has not been issued by the Designated body, may be carried out only if the product marking is in accordance with the requirement

set out in point 1.0.5. of Annex 2 and if the instructions are drawn up in accordance with the point 1.0.6. of Annex 2.

3.1. The confirmation of conformity of the individual products

The Designated body carries out appropriate examinations and tests of products in accordance with point 4.1. of Annex 5 in order to check the conformity of the product with the approved type described in the foreign Type Examination Certificate and with the applicable requirements of this Rulebook.

3.2. The confirmation of conformity of the product type

The Designated body carries out appropriate examinations of the specimen(s) of the product type described in the foreign Type Examination Certificate and check the documentation of conformity in order to verify the conformity of the product type with the applicable requirements of this Rulebook and to verify that the manufacturer applies the appropriate procedure for conformity assessment in the production control stage.

4. The Designated body draws up a report in relation to the activities it carried out in accordance with the applied procedure set out in point 3. of this Annex and, if by carrying out such procedure the conformity of the product, or of the product type, has been verified, the Designated body shall issue to the applicant the confirmation of conformity referred to in point 4.1. of this Annex.

4.1. The confirmation of conformity

The confirmation of conformity shall contain, in particular: reference to this Rulebook, the name and identification number of the document, identification of the applied confirmation of conformity procedure, the name and address of the manufacturer, the name and address of the applicant; the identification and description of the product type (name and description, category, type designation), identification of individual product(s) the conformity of which has been confirmed, where the procedure referred to in point 3.1. of this Annex has been carried out; references of certificate(s) on the basis of which the conformity of the product has been confirmed, i.e. the certificate number and the identification of the issuing foreign conformity assessment body (name, identification number of the Designated body), symbols and markings on the product, in relation to its intended use, in accordance with point 1.0.5 of Annex 2 or the relevant certificate issued by the Designated body, the conditions for the validity of the confirmation of conformity, if any; where applicable, the expiration date of the confirmation of conformity (in accordance with the expiration date of the certificate issued by the Designated body involved in production control stage); date of issue of confirmation of conformity and the identification and signature of the authorised person.

4.2. After obtaining of the confirmation of conformity for a product type in accordance with point 3.2. of this Annex, the manufacturer, the representative or the importer ensures that each individual product placed on the market is in conformity with the confirmed type and, when deemed appropriate with regard to the risks presented by the product, ensure that appropriate sample testing and/or examination is carried out by the Designated body of his choice.

5. The Designated body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the confirmed type may no longer comply with the applicable requirements of this Rulebook, and shall determine whether such changes require further investigation and shall inform the manufacturer accordingly

The manufacturer, the representative or the importer must inform the Designated body of all modifications to the confirmed type that may affect the conformity of the product with the requirements of this Rulebook and on changes to the certificate(s) on the basis of which the conformity of the type has been confirmed. Such modifications/ changes shall require additional approval in the form of an addition to the original confirmation of conformity.

6. The Designated body keeps a public register of issued confirmations of conformity and must provide the designating authority, periodically or upon request, with the lists of the confirmations of conformity it has refused, suspended or otherwise restricted.

At the request of competent authorities, the Designated body shall provide them with copies of the confirmation of conformity, of the documents provided by the applicant and of the reports drawn up in relation to activities it has carried out.

The Designated body must keep a copy of the confirmation of conformity, reports in relation to activities carried out in accordance with point 3. of this Annex, as well as the document provided by the applicant, for at least 10 years after the confirmation of conformity was issued.

7. The conformity marking

Before placing the product on the market, the manufacturer, the representative or the importer, on the basis of the obtained confirmation of conformity, affixes the Serbian conformity marking, followed by the Designated body’s unique identification number and the last two digits of the year of issue, to the product or, if that is not possible or warranted, to the product’s packaging or to a document accompanying it.