GUIDE FOR THE IMPLEMENTATION OF THE PPE RULEBOOK

Belgrade, October 2020

CONTENT

Introduction (legal basis, structure and link to EU regulations)

The legal basis for the adoption of the Rulebook on personal protective equipment ("Official Gazette of RS", No. 23/20 hereinafter "Rulebook") is contained in Article 6, paragraph 1 of the Law on Technical Requirements for Products and Conformity Assessment ("Official Gazette RS ", No. 36/09 - hereinafter" the Law "), which stipulates that the technical regulation is prepared and adopted by the Ministry within its scope. This rulebook was adopted by the Minister of Economy, as the competent minister in the field of technical requirements for industrial products. The Rulebook was published on March 10, 2020 and entered into force on March 18, 2020.

This Rulebook prescribes: essential requirements for health and safety as well as other requirements and conditions that must be met by personal protective equipment before being placed on the market and / or used, in order to protect the health and safety of users of that equipment; categories and types of personal protective equipment; assessment procedures and assessment; presumption of conformity; content of technical documentation; the content of the Declaration of Conformity; mark of conformity and marking of conformity; safeguard clause and requirements that a conformity assessment body must meet in order to be appointed for conformity assessment.

The Rulebook is in line with EU Regulation 2016/425 of the European Parliament and of the Council of 9 March 2016 on harmonisation of regulations of Member States on personal protective equipment , which is in line with the obligations of the Republic of Serbia under the Stabilization and Association Agreement (SAA), as and from the National Programme of Integration of Serbia into the European Union (NPI) in connection with the transposition of the directives of the European Union (EU) into national legislation, or harmonisation of national legislation with the EU acquis. Obligations from the SAA relate in particular to the part related to the free movement of goods and in that sense, the need to harmonise the technical legislation of the Republic of Serbia with EU technical legislation in order to remove unnecessary technical barriers to trade as one of the key elements to ensure free movement of goods and ensure the creation of a single market.

In accordance with EU Regulation 2016/425 of the European Parliament , as a regulation of the so-called "New Approach" in the field of EU technical legislation and the Law on technical requirements for products and conformity assessment foreseen solutions in field of PPE, the type of entities that carry out conformity assessment, the type of documents of compliance, as well as the manner of proving compliance which reflected in the voluntary application of Serbian standards which take over harmonised (European) standards in this area.

Namely, this Rulebook, in accordance with the adopted Regulation, prescribes only the essential requirements for the protection of health and safety related to personal protective equipment (Article 5 and Annex 2) , and detailed safety requirements and other technical requirements for personal protective equipment contained are in Serbian standards which take over harmonised (European) standards.

This instruction does not represent an official interpretation of the Rulebook, but should serve all interested parties, in order to facilitate the application of the Rulebook. Stakeholders are primarily producers, distributors and users of PPE (the Rulebook is of special importance for employers who have the obligation to ensure the use of PPE by their employees within the measures of occupational safety and health protection), as well as designated conformity assessment bodies (hereinafter: Designated bodies).

This Rulebook is accompanied by a list of Serbian standards in the field of PPE that is compiled and published by the Minister of Economy in the "Official Gazette of the Republic of Serbia", in accordance with the law, this Rulebook and a special regulation. These are Serbian standards by which the harmonised (European) standards in the field of personal protective equipment are taken over, issued by the Institute for Standardisation of Serbia, and which application fulfills the presumption of compliance of personal protective equipment with the essential requirements of this rulebook.

Structure of the Rulebook

The Rulebook contains 6 sections and 10 annexes.

In the first section, the introductory provisions first prescribe the subject, the area of application, ie. products to which the Rulebook applies and products to which the Rulebook does not apply, and definitions of key terms in the Rulebook. The second section refers to the obligations of PPE suppliers, producers, agents, importers, distributors, special obligations of importers and distributors and identification of suppliers. The third section deals with the presumption of conformity, the declaration of conformity and the marking of conformity.

The fourth section contains provisions on the categorisation of PPE, prescribes the procedures for assessing the conformity of PPE and the requirements for the notified body, gives an assumption on the fulfillment of the requirements for the notified body as well as the requirements for the notified body in relation to its subcontractors.

The fifth section contains provisions related to the supervision of PPE and the safeguard clause, the treatment of PPE that poses a risk, as well as the treatment of compliant PPE that poses a risk, and defines formal non-compliances.

The sixth section contains transitional and final provisions related to the marking of PPE compliance in connection with Serbia's accession to the EU and the signing of the ACAA agreement, provisions on termination of previous regulations in this area and obligations of conformity assessment bodies in accordance with this Rulebook until the end of designation procedure, validity of documents on compliance in the transitional period until April 21, 2023.

In Annex 1 PPE is classified into categories. Annex 2 contains provisions on essential health and safety requirements for PPE. Annex 3 prescribes the content of the technical documentation of PPE. Annexes 4 to 8 contain descriptions of conformity assessment procedures, for different categories of PPE. Annex 9 refers to the content of the Declaration of Conformity PPE and Annex 10 to the appearance and content of the Serbian mark of conformity and the CE mark.

Previous PPE Directive

New European Regulation of PPE (EU) 2016/425 based to the previous PPE Directive 89/686/EEC. This Directive was a directive on full harmonisation, ie. its provisions have replaced the existing different national and European regulations covering the same topics.

Directive 89/686/EEC is applied from 1 July 1992 and remained in force until 20 April 2018 , in accordance with Article 46 of the Regulations is the PPE. However, Article 47 provides for special transitional provisions, in particular allowing products to be placed on the market in accordance with the Directive until 20 April 2019.

Directive 89/686/EEC was transposed into the technical legislation of the Republic of Serbia by the Rulebook on personal protective equipment ("Official Gazette of the RS", No. 100/11)

The withdrawal of the previous Directive 89/686/EEC is prescribed by Article 46 of the Regulation on PPE (EU) 2016/425 and the date of entry into force isof the 21 April 2018. However, Article 47 provides for special transitional provisions, in particular to allow the placing on the market of products complying with the Directive until 20 April 2019.

On the day of the beginning of the application of this Rulebook , ie from March 18, 2020, the Rulebook on personal protective equipment ceases to be valid ("Official Gazette of RS", No. 100/11).

1. CHAPTER I – INTRODUCTORY PROVISIONS

1.1. Article 1 - Subject

Subject

Article 1

This Rulebook prescribes: essential requirements for health and safety, as well as other requirements and conditions that must be met by personal protective equipment (hereinafter: PPE) before being placed on the market and / or used, in order to protect the health and safety of users of that equipment. ; categories and types of personal protective equipment; conformity assessment procedures; presumption of conformity; content of technical documentation; the content of the Declaration of Conformity; mark of conformity and marking of conformity; safeguard clause and the requirements that a conformity assessment body must meet in order to be appointed for conformity assessment.

The Rulebook applies to personal protective equipment (PPE) intended for home use, use in leisure and sports activities, as well as PPE for professional use.

The objectives of the PPE Rulebook are:

- providing the essential requirement for health and safety (hereinafter referred to as "ERHS") that PPE must satisfy in order to ensure the protection of the health and safety of users that it is intended for;
- ensuring the free movement of PPE.

1.2. Article 2 - Implementation

The Rulebook applies to each individual PPE that is placed on the market. Rules are not applicable to clothing intended for personal use with lights in high-speed or fluorescent elements involved only because of design or as a garnish. However, if the producer claims that the product has a protective function, or if the product is sold for use as PPE, it must meet the applicable requirements of the Rulebook . If the information provided or the appearance of the product may give the impression that the product can be used as a high visibility PPE, then the product must meet the applicable requirements of the Rulebook, unless there is a clear warning that the product is not intended for use as a PPE.

Protective creams, such as creams for protection against natural UV radiation, are not PPE according to the Rulebook because the definition of PPE is not met. PPE designed and manufactured for military or police purposes means that the PPE is designed and intended to be used exclusively for such purposes. This exclusion applies to all categories of PPE. However, PPE that can be used by the armed forces or can be used to maintain public order and peace that is not specifically designed for their use is covered by the Rulebook, for example, high visibility clothing with a police logo.

Implementation

Article 2

This Rulebook applies to PPE referred to in Article 3, paragraph 1, item 1) of this Rulebook. This policy does not apply to:

1) PPE designed and constructed specifically for the armed forces or for the maintenance of public order and peace;

2) PPE designed for self-defense, with the exception of PPE intended for sports activities;

3) PPE designed and constructed for private use used for protection against:
(1) atmospheric influences that are not of an extreme nature,

(2) moisture and water when washing dishes;

4) PPE intended exclusively for use on seagoing vessels or aircraft, in accordance with special regulations;

5) PPE for the protection of the head, face or eyes of the user, covered by a special regulation relating to protective helmets and their visors intended for motorcycle and moped riders and their passengers.

The equipment used by firefighters according to the Rulebook is PPE. Protective equipment that is bulletproof and knife-stabproof, for example, for officers of security, is the PPE and is not covered by the exclusion relating to the armed forces or the maintenance of public order and peace. The producer is allowed to use the requirements of this Rulebook or the corresponding harmonised European or Serbian standards when designing and manufacturing protective equipment exclusively for use in the armed forces or in maintaining public order and peace, but this PPE must not be marked with the Serbian mark of conformity or CE mark unless required by another regulation.

Equipment intended for use in self-defense is excluded from the Rulebook. Examples of such equipment are aerosol canisters and personal deterrent weapons.

Equipment intended to protect against injuries in self-defense sports activities, such as fencing protective equipment or protective equipment for martial arts such as karate (see standards of the EN 13277 series), is covered by the Rulebook. This special "exclusion from exclusion" was introduced in the Rulebook to ensure that these types of PPE for sports activities remain covered by the Rulebook.

PPE designed and manufactured for personal use for protection against the weather (atmospheric) conditions, including, but not limited to, seasonal clothing, for example clothing for rain and clothing that protects from the cold , which is not extreme, does not fall within the scope of application of the Rulebook . Natural UV radiation (sunlight) is not an atmospheric state.

However, PPE for professional use designed and constructed for protection against weather conditions that are neither exceptional nor extreme is subject to the Rulebook . For example, rainwear and cold protection under normal weather conditions for professional use are included in the scope of the Rulebook .

Gloves for washing dishes for personal use, exclusively designed and manufactured for protection from moisture and water, do not fall within the scope of application of the Rulebook .

Protect the equipment for personal use , which protects against heat (eg oven gloves), which has not been classified previously as PPE, is included in the Rulebook . Decorative products that are not claimed to protect from heat, for example hand-knitted "pot holders" from the bazaar with only a decorative function, by definition are not PPE . PPE intended for the protection or rescue of persons on marine vessels or in aircraft, to strengthen not worn all the time, ie. is used only in case of emergency is not the subject of this Regulation but special regulations apply to it .

1.3. Article 3 - Definitions

The area of PPE is not limited to equipment used by employees or workers, but extends to non-work-related areas, such as sports and recreational activities. Sunglasses, helmets for cycling or riding, garden gloves, umbrellas for football players, hiking belts, all these are PPE activities . This definition has proved easy to understand for equipment producers and users, although there are still some borderline cases. Every expression in the definition is important:

The meaning of certain expressions

Article 3.

Certain expressions used in this Rulebook have, in terms of this Rulebook, the following meaning:

1) personal protective equipment (PPE) – is equipment designed to be worn or held by the user for their own protection against one or more health and safety hazards, as well as:

(1) replaceable PPE components that are relevant to its protective function,

(2) PPE connection systems that are not intended for the user to hold or wear, which are designed to connect that equipment to an external device or reliable anchor, which are not designed to be permanently attached and do not require attaching before use;

2) delivery on the market – is any act of making PPE available on the market of the Republic of Serbia for distribution or use, within economic activity, with or without compensation;

3) putting on the market – is the first delivery of PPE on the market of the Republic of Serbia;

4) manufacturer – is a legal entity or entrepreneur that manufactures PPE or for whom the PPE is designed and made and who puts the PPE on the market under their business name or trademark;

5) representative – is any legal entity or entrepreneur registered in the Republic of Serbia who has the written authority of the manufacturer to take certain actions on their behalf;

6) importer – is a legal entity or entrepreneur registered in the Republic of Serbia, which puts PPE from other countries on the market;

7) distributor – is a legal entity or entrepreneur registered in the Republic of Serbia, which is included in the supply chain and is not a manufacturer or importer;

8) the supplier – is the manufacturer, representative, importer or distributor;

9) technical specification – is a document determining the technical requirements to be met by the PPE;

10) harmonised standard – is the European standard enacted on the basis of the European Commission's request for implementation in harmonised Legislation of the European Union;

11) accreditation – is the determination by the national accreditation body that the conformity assessment body meets the requirements of the appropriate Serbian standards by which harmonised standards have been taken and, when applicable, all additional requirements defined for certain areas, in order to perform certain compliance assessment tasks;

12) assessment of conformity – is a procedure that determines whether important health and safety requirements of PPE have been met;

13) the conformity assessment body – is a legal entity that conducts conformity assessment activities, which includes etalonisation, examination, certification and/or control;

14) recall – is any measure aimed at recalling the PPE that has already been delivered to the end user;

15) withdrawal – is any measure aimed at preventing the PPE from delivering to the market in the delivery chain;

16) harmonised EU legislation – are EU regulations that harmonise the conditions for trading products;

- PPE is "worn" in the sense of wearing clothes, glasses, hearing protection or a fall arrest. In fact, a good part of PPE is clothing, whether it is clothing, headgear, gloves or shoes. The rest of the PPE should be "held" in the hand, such as eye and face protection during welding. Whether PPE will be worn or kept depends on the action of the person who is exposed to danger.

Portable equipment that is not worn or held during use is not considered personal protective equipment. Thus, for example, insulating mats or tables used by electricians during work and live or protective curtains placed on workstations are not considered PPE.

- PPE is carried or held by a "person". This distinguishes personal protective equipment from collective protective equipment.

- PPE is used to protect the individual. The equipment mainly consists of a shield between the body part and endangerment to protect the individual from any kind of risk: a shield made of leather to protect against rough surfaces that can scratch the skin on the hands, a shield made of filter glass to protect against radiation that can injure the eyes. X-rays that can damage body cells, and so on. This protective role of PPE is emphasized by pictograms, which are sometimes chosen in accordance with PPE standards that symbolize protection against various hazards: the symbol representing the danger is displayed in the shield.
  On the other hand, equipment that warns of risks, but which does not have a protective function, such as specific alarm devices, e.g. gas detectors or oxygen deficiency detectors, are not classified as PPE. However, if these devices are integrated into the PPE, they will be considered an integral part of the PPE.
- PPE protects against "one or more risks". Risk can be defined as a combination of two elements: danger, which is a phenomenon that can cause damage, and the probability that a person will be exposed to that danger. Since PPE is designed to protect against risk, its function is to prevent damage to the exposed person . Therefore, when at the same time there are a few risks, PPE must protect against all risks, not just from one of them.

This distinguishes PPE from equipment used after an injury has occurred, such as rescue equipment or first aid equipment, which is also used by third parties. Equipment used by a rescuer is not classified as PPE unless it is used to protect the rescuer himself, for example, respiratory protection devices used by firefighters when pulling people out of burning and smoky buildings.

Equipment with non-automatic protective function, ie. equipment where the protective function must be activated manually is considered to be PPE subject to the Rulebook.

The risks involved are those that may harm the equipment user. Equipment used to protect people other than users, such as masks used to protect hospital patients, is not PPE. However, all equipment worn by medical staff for their own protection is PPE. Similarly , equipment for the protection of goods, such as gloves worn to protect foodstuffs or electronic components, is not PPE.

Interchangeable components are components used exclusively for the equipment referred to in Article 3 (1). This category includes, for example, filters for respiratory protection devices and filters for eye protection during welding. They are key to the protective function and are part of the equipment listed in Article 3 (1).

PPE items that need to be replaced with original parts or parts according to the instructions and information of the producer, and which do not affect the protective function of PPE are not covered by this definition . For example, hygienic pads for earmuffs and sweat straps for protective helmets.

Coupling systems are considered personal protective equipment when no tools are required to fasten or remove the coupling system. The air supply pipe that connects the respiratory protection device to the compressor is an example of a connection system.

In contrast, a coupling system is not a PPE when it is permanently fixed and when tools are needed to fasten or remove the coupling system to or from a structure. For example, anchoring devices that are part of the structure or require tools for installation, for example in the buildings and machines, not considered to be PPE.

Delivery on the market is any making available of products on the market of the Republic of Serbia for distribution, consumption or use, with or without compensation, and placing on the market is the first delivery of products to the market of the Republic of Serbia; PPE placed on the market must comply with the applicable regulations at the time of placing on the market.

The producer is a legal entity or entrepreneur who manufactures PPE or for whom the PPE is designed and manufactured and who places the PPE on the market under their business name or trademark. By definition, a producer can design and manufacture PPE themselves or can use purchased products, subcontractor services or components, to assist in the production of PPE.

Whoever substantially alters PPE that is already placed on the market, affecting its health and safety characteristics (and/or performance), resulting in a "new" product , with a view to its placing on the market, also becomes the producer.

The obligations of the producer also apply to any natural or legal person who compiles , packs, processes or marks the finished PPE and places it on the market under their name or trademark.

Representative is any legal entity or entrepreneur registered in the Republic of Serbia that has a written authorisation of the producer to take certain actions on their behalf . The extent to which the representative may assume obligations relating to the producer shall be limited to the articles of the Rulebook and shall be determined by the power of attorney granted to him by the producer.

Once appointed, representatives are required to make the declaration of conformity and technical documentation available to the competent authorities ; upon the request of the competent authorities, provide the information and documentation necessary to demonstrate the conformity of the product; to cooperate with the competent state authorities in all actions taken to eliminate the risks posed by products covered by their authorisation . They can be be appointed also to set a sign of conformity or the preparation and signing of the declaration of conformity .

Importer is a legal entity or entrepreneur registered in the Republic of Serbia, which places PPE on the market from other countries.

A distributor is a legal entity or entrepreneur registered in the Republic of Serbia, which is included in the supply chain, and is not a producer or importer .

This is a very general concept that includes different types of technical requirements for PPE or categories of PPE, in accordance with applicable regulations and/or sectoral provisions. Technical specifications are provided by standards or any other technical document prepared by authorised experts, as well as public or private organisations. They can establish a "minimum" as " essential requirements" or they can be more detailed in terms of specific technical solutions for the design and manufacture of PPE.

Conformity assessment is a procedure carried out by the producer, showing whether certain requirements related to PPE are met.

PPE undergoes conformity assessment both during the design phase and during the production phase. The producer is responsible for assessing conformity. If the producer leaves the design or construction to a subcontractor, he remains responsible for carrying out the conformity assessment.

The essential goal of the conformity assessment procedure is to show that the products placed on the market comply with the requirements expressed in the provisions of the relevant regulations.

Conformity assessment bodies (designated bodies in accordance with the Rulebook) make professional and independent assessments, which in turn allows producers or their representatives to comply with the procedures for presuming compliance with the Rulebook. Their participation is required on the:

- issuance of a certificate of examination of type, after control, verification and testing of PPE in terms of meeting the essential requirements for health and safety before they can be placed on the market;
- conformity assessment of manufacture according to the methods set forth in Annexes 7 and 8 for the PPE of Category III.

The competent state authorities must take measures to ensure compliance , when they find that PPE is not in accordance with the applicable provisions of the Rulebook.

Acting against the inconformity can be achieved by making producer, representative or other responsible persons to take the necessary measures, including recall and withdrawal of PPE from the market.

In the event of an informal inconformity, authorities of market surveillance would first need to oblige the producer or representative to comply PPE which they intend to put on the market and, if necessary, and PPE that is already on the market, with regulations and eliminate inconformity.

1.4. Article 4 - Delivering on the market

PPE is delivered on the market when it seems available for distribution, consumption or use within an economic activity, with or without compensation. This concept of "making available" applies to each individual PPE.

Delivery on the market

Article 4

PPE is delivered on the market only if, with proper maintenance and use for its intended purpose, it meets the requirements of this Rulebook, i.e. if it does not endanger the health or safety of other people, domestic animals or property.

The concept of “placing on the market” is directly related to “making available” in the sense that PPE is placed on the market when it is first made available. PPE placed on the market must comply with applicable regulations .

1.5. Article 5 - Essential requirements for health and safety

Article 5 establishes the obligation of producers to design and produce PPE which satisfies the requirements of Annex 2 of the Rulebook. The producer shall ensure that the requirements remain met over the life of the PPE.

Important health and safety requirements

Article 5

The PPE must meet the essential health and safety requirements that apply to that PPE. Important requirements for health and safety of PPE (Annex 2), is printed with this Rulebook and is an integral part of it.

Only PPE that meets these requirements can be placed on the market . The producer must provide information on the measures taken to ensure compliance of the PPE with the requirements in their technical documentation, which is further specified in Article 8 and described in detail in Annex 3 of the Regulation.

The requirements deal only with product characteristics aimed at protecting the health and safety of users. They cover neither social aspects nor environmental aspects .

These requirements are designed to provide an optimal level of user protection against risk. They:

- arise from certain risks to which the user is exposed, in relation to the product, for example physical, mechanical, exposure to heat and flame, chemical, electrical, biological, hygienic or radioactive risks;
- relate to PPE and / or its performance, for example to provisions relating to materials, design, construction, manufacturing process, instructions drawn up by the producer;
- determine the basic objectives of protection, for example, by means of an illustrative list;

1.6. Article 6 - Provisions relating to the use of PPE

Special requirements for the use of PPE

Article 6

A special technical regulation may determine special requirements related to the use of PPE, provided that these requirements do not affect the design of PPE that is placed on the market in accordance with this Rulebook.

Member States keep the right to establish additional national provisions regarding the use of PPE aimed at ensuring the protection of workers or other users.

1.7. Article 7 - Free circulation

The Rulebook does not stipulate obligations for users. However, it should be borne in mind that employers have obligations regarding the use of work equipment in the workplace.

Free trade

Article 7

PPE, which meets all the requirements and conditions in this Rulebook, is delivered to the market freely, without any restrictions.

Exceptionally, PPE that does not meet the requirements and conditions of this Rulebook can be publicly exhibited and shown at the markets, exhibitions, presentations and other similar events, provided that it is marked in plain sight by a warning that this PPE does not comply with the requirements of this Rulebook and to prohibit its delivery until it meets the requirements of this Rulebook.

During the exposure and/or display of PPE from Paragraph 2 of this Article, manufacturer or exhibitor are obliged to take appropriate security measures for the protection of people.

The second paragraph of Article 7 refers to exhibiting of PPE that is not in accordance with the Rulebook at exhibitions . Exhibiting PPE at a trade or retail fair does not constitute "placing on the market".

2. CHAPTER II - OBLIGATIONS OF SUPPLIERS OF PPE

Chapter II of the Rulebook deals with the obligations and identification of producers, agents , importers and distributors, jointly defined as suppliers . These are active roles in the supply chain when PPE is made available on the market and in that sense special obligations and responsibilities are defined. It should be noted that the users (consumers, workers ...) are not considered as " business entities" within the meaning of the Rulebook .

2.1. Article 8 – Obligations of producers

Manufacturer Liabilities

Article 8

The manufacturer , when putting PPE on the market, ensures that the PPE is designed and developed in accordance with applicable important health and safety requirements from Annex 2 of this Rulebook.

The manufacturer is obliged to compile technical documentation for the PPE, in accordance with this Rulebook, and to implement the appropriate conformity assessment procedure under Article 18 of this Rulebook.

Technical documentation for PPE (Annex 3) is printed with this Rulebook and forms an integral part of it.

If the application of the appropriate conformity procedure proves compliance with applicable important health and safety requirements, the manufacturer makes up the Declaration of Conformity under Article 15 and puts up a mark o conformity under Article 16 of this Rulebook.

The manufacturer stores technical documentation and the Declaration of Conformity for ten years after PPE was put on the market.

The manufacturer provides appropriate procedures that achieve the continuity of fulfillment of the requirements in the case of PPE serial production, which appropriately takes into account changes made to the project or characteristics of the PPE, as well as changes to applied standards or other technical specifications on which the PPE compliance is declared.

When appropriate in relation to the risk posed by the PPE, in order to protect the health and safety of consumers and other end users, the manufacturer examines PPE samples on the

market, processes information and keeps records of advertising, as well as conflicting and recalled products, and informs distributors.

The manufacturer ensures that the PPE they put on the market is marked with a type, party, serial number, or other identification data, or, if this is not possible because of the size or type of PPE, they ensure that this data is listed on the packaging or document that accompanies the PPE.

The manufacturer lists in the PPE their business name, registered trade name or registered trademark, as well as their contact address, or if that is not possible, lists this data on the packaging or document that accompanies the PPE.

The manufacturer ensures that the PPE follows the prescribed instructions and information in Serbian, which are clear, understandable and readable, i.e. other prescribed documentation in accordance with Article 1.4 of Annex2. of this Rulebook.

The manufacturer attaches the Declaration of Conformity to the PPE or provides its availability on its official website, where the address of the website is listed in the instructions for use.

A manufacturer who believes or has reason to believe that the PPE they have placed on the market is not compliant with this Rulebook, without delay takes the necessary corrective actions in order to harmonise the PPE or, if appropriate, to withdraw or recall it. Also, if the PPE poses a risk, the manufacturer immediately notifies the competent authorities, citing details especially about the identified conflict, and all corrective actions taken.

At the request of the competent authority, the manufacturer submits information, i.e. documentation, in paper or electronic form, necessary for confirmation of the conformity of the PPE, in Serbian.

The manufacturer cooperates with the competent authorities, at their request, in all actions taken to avoid the risks posed by the PPE that they have placed on the market.

The producer is solely and ultimately responsible for the compliance of their PPE with the applicable regulations . They must understand both the design and development of PPE in order to be able to declare such conformity in accordance with all applicable regulations and requirements of the relevant regulations .

In this case , if PPE has been produced for 5 years, the data must be kept for at least 15 years (counting from the placing on the market of the first PPE from the series).

An important point in Article 8 is that the type, lot , or a serial number must be clearly associated to the documentation that demonstrates the conformity of certain types of PPE, and especially Declaration of conformity. Producers must be aware that, even on it is not possible to distinguish the series or serial number when authorities for market surveillance product recall , all products of this type or series shall be removed from the market. Rulebook allows placing information on the package or if the size or nature of the product to prevent, in the documentation that accompanies the product. If the information is not visible at first glance, it must be easily and safely accessible.

Instructions and information for use provided by the producer must be written in Serbian .

Producer's instructions and information make one of the essential elements of any PPE and as such must be clear, concise, understandable and provide appropriate information to end users. It should be noted that the producer's instructions and information can only be considered

effective if they are easily observed and understood, remembered and used appropriately . Given the fact that the instructions and information producers provide the basis on which consumers can select the corresponding PPE, are classified in another of the means to protect the health and safety of the end user . The better the information , the easier the choice and the correct use of PPE and the lower the risk of wrong selection.

The instructions for use follow each individual PPE or each lot of identical products delivered to the same end user.

To improve instruction and information producers, font size should be as big as possible in order to help readers. The readability of the text is also affected by the contrast between the color of the letter and the color of the surfaceon which it is printed, as well as the opacity of the surface .

For the purposes of market surveillance, among other things, Declaration of conformity in Article 8 must be accompanied by instructions for use and internet address where te Declaration can be accessed, including instructions for use. If they opt for the Internet, producers can use of it different solutions (eg. direct web address, a generic web page with search function), but it must be ensured that the Declaration of conformity is easily accessible by this route.

Articles 14-19 and related annexes of the Rulebook define the producers' obligations in relation to conformity assessment, sign, Declaration of conformity, as well as ways of keeping Declaration of conformity and the technical documentation so that they are available to the competent state authorities for a period of 10 years after which is the last single PPE placed on the market.

2.2. Article 9 - Obligations of representatives

Article 9 of the Rulebook defines the role and possible tasks of a representative registered under the authority of the producer: this kind of authorisation must include at least certain activities relating to conformity assessment, sign, Declaration of conformity, as well as the way making Declaration on conformity and technical documentation available to the competent authorities in the period of 10 (ten) years after the last individual PPE was placed on the market.

Obligations of representatives

Article 9

The manufacturer may give a written authorisation to the representative to perform certain obligations, which must enable the representative to at least:

1) make the Declaration of Compliance and Technical Documentation available to the competent market surveillance authorities for at least ten years after placing PPE on the market;

2) submit to the competent authorities, upon the request, all information and documentation necessary to confirm the conformity of the PPE;

3) cooperate with the competent authorities, upon request, in all actions taken to avoid the risks posed by the PPE covered by the manufacturer's authorisation. The manufacturer cannot authorsze the representative to perform the obligation under Article 8. Paragraph 1. of this Rulebook, nor for the drafting of technical documentation.

2.3. Article 10 - Obligations of importers

The importer has important and clearly defined obligations in accordance with the Rulebook , largely based on the type of obligations to which the producer is subject to. The importer ensures the proper fulfillment of the producer's obligations . The importer is not a simple reseller of the products but has a key role in ensuring compliance of imported products. On the embroidered products the name and address of the producer and the importer must be indicated, as a basic condition of traceability for market surveillance.

Obligations of importers

Article 10

The importer is obliged to put on the market only the PPE which is compliant with the requirements of this Rulebook.

The importer ensures, prior to placing thePPE on the market, that the prescribed conformity assessment procedure has been implemented in accordance with Article 18 of this Rulebook and that the manufacturer has compiled the necessary technical documentation. The importer ensures that the product is marked with a prescribed mark of conformity, i.e. other prescribed markings, to be accompanied by prescribed documentation and that the manufacturer has fulfilled their obligations to provide prescribed data in accordance with Articles 8 and 9 of this Rulebook.

Exceptionally, for the PPE that is imported into the Republic of Serbia, placing a mark of conformity can be performed also by the PPE importer, in accordance with regulations governing the implementation of conformity assessment and the manner of placing and using mark of conformity.

An importer who believes or has reason to believe that the PPE is not compliant with the applicable important requirements of this Rulebook puts the PPE on the market only after compliance with these requirements and, if it poses a risk, informs the manufacturer and the competent market surveillance authorities.

The importer lists their business name, registered trade name or registered trademark, as well as their contact address, or if that is not possible, lists this data on the packaging or document accompanied by the PPE.

The importer ensures that the PPE follows the prescribed instructions and information in the Serbian language compiled by the manufacturer, i.e. other prescribed documentation in accordance with Annex 2 from this Rulebook.

The importer ensures that while the PPE is under their responsibility, the conditions of storage or transport do not endanger the compliance of the PPE with the prescribed requirements.

When appropriate in relation to the risk posed by the PPE, in order to protect the health and safety of consumers, the importer examines PPE samples on the market, processes information and, if necessary, keeps records of the advertisements, as well as conflicting and recalled PPE, and informs distributors.

An importer who believes or has reason to believe that the PPE they have put on the market is not compliant with this Rulebook, without delay takes the necessary corrective actions in order to harmonise or, if appropriate, to withdraw or recall it. Also, if the PPE poses a risk, the

importer immediately notifies the competent authorities, citing details especially about the established conflict, and all corrective actions taken.

The importer makes available a copy of the Declaration of Conformity and Technical Documentation to the competent market surveillance authorities, upon their request, for at least ten years after the PPE was put on the market.

Upon the justified request of the competent authorities, the importer submits information, i.e. documentation, in paper or electronic form, necessary for confirmation of the Conformity of the PPE, in Serbian. The importer cooperates with the competent authorities, upon their request, in all actions taken to avoid the risks posed by the PPE they have placed on the market.

2.4. Article 11 – Obligations of distributors

In addition to producers and importers, distributors are the third category of economic entities that are subject to special obligations. A distributor is a natural or legal person in the supply chain, other than the producer or importer, who makes the products available on the market.

Distributors are, for example, required to know which products must carry a sign of conformity , which information must be submitted with the product (for example, Declaration of conformity), what are language requirements for labeling , instructions for users or other supporting documents, and what is a clear indicator of product non-conformity . Distributors are obliged to show the market surveillance authority that they acted with care and made sure that the producer or his representative or the person who provided them with the product took the measures prescribed by the Rulebook.

Conformity assessment, preparation and storage of Declaration of conformity and technical documentation remain the responsibility of the producer. In case of a change in regulations, the distributor is not obliged to check whether the product that has already been placed on the market still complies with the legal obligations currently in force. Distributors' obligations relate to the regulations that were in force at the time of placing the product on the market by the producer and or importer.

The distributor must be able to identify the producer, their representative , the importer or the person who had provided the product in order to help the market surveillance authority in obtaining Declaration of conformity and the needed technical documentation. Market surveillance authorities have the possibility to send their request for technical documentation directly to the distributor. However, distributors are not expected to have proper documentation.

Obligations of the distributor

Article 11

When delivering PPE on the market, the distributor is obliged to act conscientiously in relation to the requirements of this Rulebook.

Before delivery of PPE on the market, the distributor is obliged to check that the PPE is marked with the prescribed mark of conformity, or other prescribed marks and data, as well as to be accompanied by prescribed instructions and information in Serbian language, or other prescribed documentation. Also, the distributor is obliged to check that the manufacturer and

importer have met the requirements specified in Article 8, para. 8 and 9, ie Article 10, paragraph 5 of this Rulebook.

If they considers or has reason to believe that the PPE does not comply with the requirements of this Rulebook, the distributor shall deliver the PPE only after it has complied with those requirements and, if that PPE poses a risk, inform the manufacturer or importer and the competent market surveillance authorities.

The distributor shall ensure that, while the PPE is under their responsibility, the conditions of storage or transport do not endanger the compliance of the PPE with the prescribed requirements.

A distributor who considers or has reason to believe that a delivered PPE has not complied with this Rulebook shall, without any delay, take the necessary corrective action to comply that PPE or, if appropriate, to withdraw or recall it. Also, if the PPE poses a risk, the distributor shall immediately notify the competent authorities, citing the details, in particular the identified non-compliance, and any corrective action taken.

Upon the justified request of the competent authorities, the distributor shall submit the information, ie documentation, in paper or electronic form, necessary for the confirmation of the conformity of PPE, in the Serbian language.

The distributor cooperates with the competent authorities, at their request, in all actions taken in order to avoid the risks posed by PPE that they have placed on the market.

2.5. Article 12 - Specific obligations of importers and distributors

The obligations of the producer also apply to any natural or legal person who compiles , packs , processes or marks the finished PPE and places it on the market under his name or trademark. Further more, obligations of the producer are applied to any person who changes purpose of PPE to the extent that the substantial or other legal requirements become applicable, or substantially modify or correct PPE (which creates a new PPE) , with the intention of placing on the market.

Special obligations of importers and distributors

Article 12

An importer or distributor who places PPE on the market under their name or trademark, or modifies PPE to the extent that it complies with the requirements of this Rulebook, shall be considered a manufacturer and assume the obligations of the manufacturer referred to in Article 8 of this Rulebook.

2.6. Article 13 - Identification of the supplier

Suppliers are obliged to keep records on suppliers which deliver PPE or that PPE was purchased from for a period of 10 years. End users are not covered by this requirement because they are not considered suppliers .

Method of execution of the request is not prescribed by the Rulebook, but it must be noted that authorities for market surveillance may request relevant documents, including invoices , which allows you to track the origin of the product. Therefore, it would be advisable to keep invoices during this period.

Supplier identification

Article 13

The supplier of PPE, at the request of the competent supervisory authority, submits data on:

1) the supplier from whom they supplied the PPE;

2) to the supplier to whom they delivered the PPE.

Suppliers shall keep the data referred to in paragraph 1 of this Article for 10 years from the date of delivery of PPE.

3. CHAPTER III - CONFORMITY OF PPE

Chapter III of the Rulebook deals with the presumption of conformity PPE and the Declaration of conformity.

3.1. Article 14 - Presumption of conformity of PPE

Presumption of PPE compliance

Article 14

It is assumed that the PPE meets the essential health and safety requirements of Annex 2 of this Rulebook, if it is prepared in accordance with Serbian standards for PPE which have adopted the relevant harmonised standards, the list of which (hereinafter: the List of Standards) is compiled and published in in accordance with the law governing the technical requirements for products and conformity assessment and the regulation adopted on the basis of that law.

The presumption of conformity of PPE is confirmed by the use of Serbian standards for PPE which take over the appropriate harmonised standards, the list of which is compiled and published in accordance with the law governing technical requirements for products and conformity assessment and regulations adopted on the basis of that law. The European standardisation organisations (ESO : CEN and CENELEC for PPE sector) and their special and technical committees, as well as other stakeholders (national experts, notified bodies, industry, etc.) are key to the development of European standards. When they become available as harmonised standards and when they are published in the Official Journal of the EU, producers generally decide to demonstrate compliance with these standards.

The use of Serbian standards is voluntary: producers can opt for other ways to meet the important health and safety requirements of the Rulebook , with additional controls relating to other requirements that are not already covered. European and Serbian standards are regularly revised and updated in response to technological developments. During the process of updating the standard, the producer may continue to use the current harmonised standard for the procedure of conformity assessment with the Rulebook , until the new harmonised standard replaces the previous one after a certain transitional period.

3.2. Article 15 - Declaration of conformity

Declaration of conformity is a legal statement of the producer or his representative confirming that the PPE placed on the market complies with all relevant provisions of the Rulebook.

After the producer takes appropriate actions for ensuring compliance with the relevant health and safety requirements of the Rulebook, the producer or their agent is required to compose a written Declaration of compliance in accordance with Annex 9 and to place a conformity mark.

Declaration of Conformity

Article 15

The Declaration of Conformity is a statement confirming compliance with the applicable essential health and safety requirements set out in Annex 2 to this Rulebook.

The content of the declaration of conformity shall be regularly updated, in accordance with the appropriate conformity assessment procedures set out in Annexes 4 to 8. from this rulebook.

If the PPE is the subject of other regulations governing other issues, which also prescribe the preparation of the Declaration of Conformity, one Declaration of Conformity is made in accordance with all applicable regulations. The said declaration shall contain an identification of the applicable regulations, with an indication of the number of official gazettes in which those regulations have been published.

By drawing up the Declaration of Conformity, the manufacturer assumes responsibility for the compliance of PPE with the requirements of this Rulebook.

The Declaration of Conformity has the content determined by this Rulebook (Annex 9), is printed together with this Rulebook and forms an integral part thereof.

Declaration of conformity must be written taking into account PPE category in accordance with Article 18.

For category II and III of PPE, when designated bodies are involved in the conformity assessment procedure, Declaration of conformity must contain the name and identification number of the title of the body, as well as number of certificate of an overview of the type . For PPE category III Declaration of conformity must contain the name and identification number of the notified body involved in the evaluation of production.

If the PPE is the subject of other regulations governing other issues, then a Declaration of Conformity is drawn up, which confirms compliance with all applicable regulations. Making Declaration of conformity and its verification , along with putting a compliance prescribed Articles 16 and 17, make the final activity in the procedures of conformity assessment. After placing the sign on PPE, the producer or his representative confirms in that the appropriate conformity assessment procedures are completed in accordance with all provisions of the Rulebook , and producer takes full responsibility for the conformity of the product.

3.3. Article16 - Marking of Conformity

From the day of application of this Rulebook until the day of entry into force of the ACAA agreement for PPE to which this Rulebook applies or, if that agreement is not concluded, until the day of accession of the Republic of Serbia to the European Union, marking of PPE conformity is done by putting the Serbian conformity mark in line with this Rulebook and special regulations. When a notified body is involved in the conformity assessment procedure referred to in Annexes 7 and 8, then the identification number of the notified body must be entered after the conformity mark .

Conformity marking

Article 16

Conformity marking shall be carried out in accordance with the law governing technical requirements for products and conformity assessment.

The mark of conformity shall be affixed to the PPE by the manufacturer or his representative in a visible place so that it is legible and indelible, in accordance with the regulation governing the manner of affixing and using conformity marks, and if this is not possible or justified due to PPE characteristics, on its packaging or documentation. which accompanies it.

PPE that has complied with the requirements of this Rulebook, before its placing on the market, shall be affixed with the mark of conformity in the manner and form prescribed by this Rulebook.

The mark of conformity (Annex 10) is printed together with this Rulebook and forms an integral part of it.

If the Designated Body has carried out a conformity assessment or participated in that assessment in accordance with Annexes 7 and 8 of this Rulebook, the unique number of that body and the last two digits of the year of issue of the compliance. The unique number of the notified body may be affixed by the notified body itself or by the manufacturer or his representative with the agreement of the notified body.

Other signs, symbols, inscriptions or other markings may be affixed to the PPE, provided that this does not reduce the visibility, legibility and / or meaning of the conformity mark.

No other signs, symbols, inscriptions or other markings may be affixed to PPE, the affixing of which is prohibited by the law governing the technical requirements for products and conformity assessment.

If a PPE is subject to other regulations governing other issues, which also prescribe the affixing of the conformity mark, the affixed conformity mark indicates that the PPE complies with the requirements of those other regulations, too.

When placed on the market, the PPE must have a Serbian mark of conformity on it or, in certain cases, on the packaging.

As a rule, the conformity mark is placed on the PPE. However, in special cases, the mark must not be placed directly on the PPE, if the conditions do not allow its placement. This would be justified if the affixing of the mark to the PPE is:

- practically impossible,
- not feasible under reasonable technical and economic conditions,
- where the minimum dimensions of the sign cannot be respected, or
- when it cannot be ensured that the sign is affixed visibly, legibly and indelibly.

In such cases, the mark of conformity must be affixed to the smallest commercially available packaging intended for the end user and to the documents accompanying the PPE.

The mark symbolises compliance with all applicable provisions of harmonis ed regulations that provide for the placement of the mark. Therefore, the affixing of marks other than pictograms or other markings indicating the risk that the PPE is intended to protect, such as a producer's mark or a voluntary quality mark that overlaps with or may be confused with a conformity mark, is prohibited.

4. CHAPTER IV - CONFORMITY ASSESSMENT

Chapter 4 of the Rulebook deals with categories of PPE and conformity assessment procedures.

4.1. Article 17 - Categories of PPE according to risk

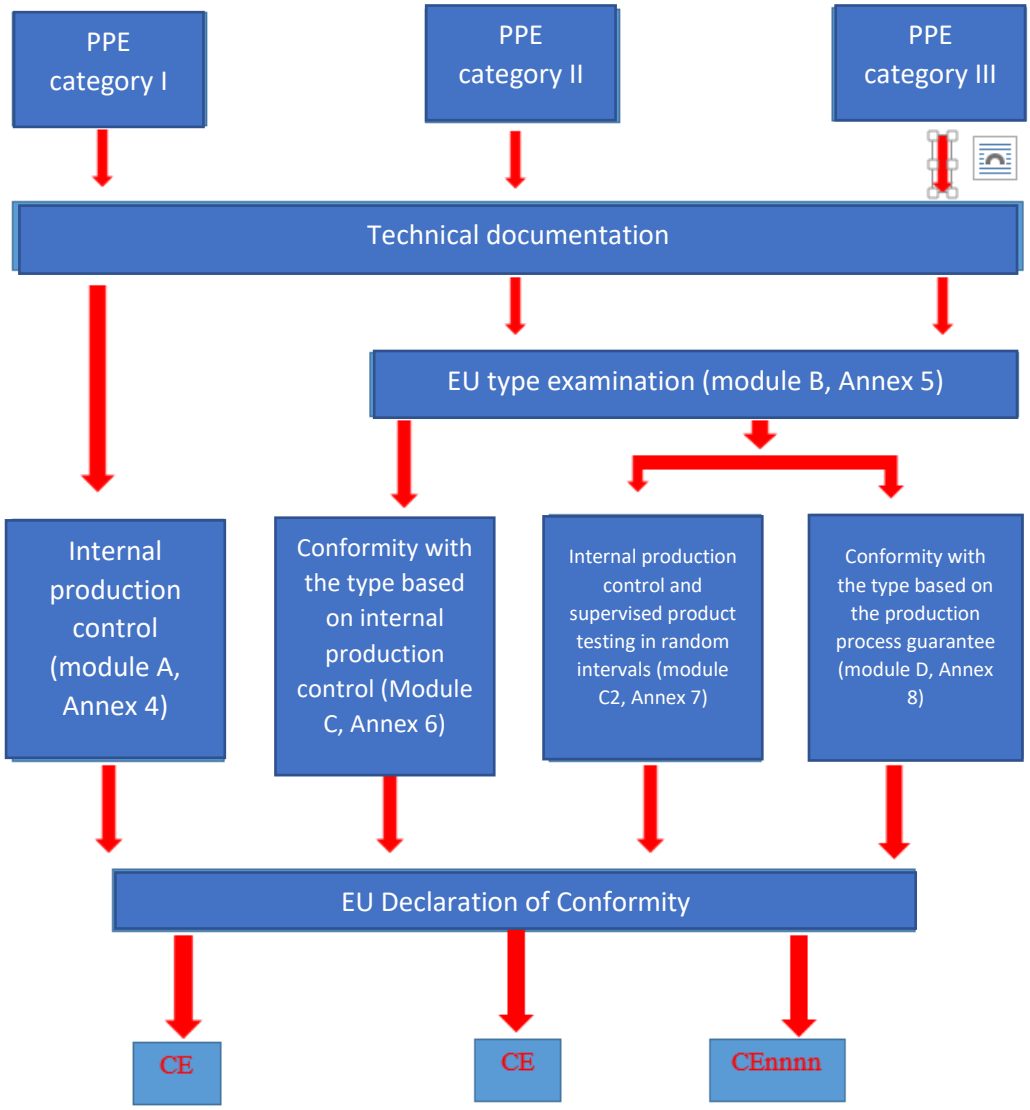
Categories of PPE according to risk

Article 17

PPE is classified into categories, according to risk. Categories of PPE according to risk (Annex 1), is printed with this Rulebook and makes an integral part of it.

Article 17 classifies the PPE covered by the Rulebook in categories I, II and III , as listed in Annex 1.

Attached to this Guide is the appendix that provides information on borderline cases and exclusions of various types of PPE.



4.2. Article 18 - Conformity assessment procedures

Article 18 sets out the relevant conformity assessment procedures for the different categories of PPE . For the PPE categories II and III , prior to initiation of the quent manufacture, model (type) PPE must be subjected to EU examination type. For PPE category III , before putting on the market, the producer shall submit to a designated body a request for supervised testing of the product in random intervals from Annex 7 of the Rulebook or for the assessment of the quality system which is specified in Annex 8 .

Conformity assessment procedures

Article 18

Appropriate conformity assessment procedures shall be conducted for each category of PPE, as follows:

1) for Category I - Internal production control (Annex 4), which is printed together with this Rulebook and forms an integral part thereof;

2) for Category II - Type examination (Annex 5), which is printed with this Rulebook and forms its integral part and Conformity with the type based on internal production control (Annex 6), which is printed with this Rulebook and forms its integral part a part of;

3) Category III. Type examination (Annex 5) from this Rulebook and one of the following procedures, as follows:

(1) Conformity to type based on internal production control and supervised testing of products at random intervals (Annex 7), which is printed with this Rulebook and forms an integral part of it;

(2) Conformity with the type based on the guarantee of the quality of the production process - quality assurance of production (Annex 8), which is printed together with this Rulebook and forms an integral part thereof.

Exceptionally, the procedure referred to in paragraph 1, item 2) of this Article may be applied to individually produced PPE, adapted to a certain user and classified in category III.

Exceptionally , on the individually produced PPE , adapted to a particular user and disaggregated in a category III , may be applied a method of point 1, the item (2) of this article.

Individually produced PPE tailored to a specific user must be tailored to the user to ensure a perfect fit and functionality. This means that such a PPE is unique . An example of an individually produced PPE tailored to a particular user is , e.g. orthopedic footwear made to measure, in which an individual product is produced for the specific medical needs of the user. Since there is only one product, production control measures are not applicable (individual product would have to be destroyed during testing and it is not possible to perform product quality assessment in accordance with Annexes 7 and 8 , because they are produced individually and not serially). Therefore, the conformity assessment procedure referred to in Article 18 (2) may be applied to this PPE . In this case it is not

possible to put thec identification number of the notified body involved in one of the procedures set out in Annex 7 and 8 behind the mark of conformity. Other products, serially produced PPE, which is necessary to be adjusted to certain users, for example, customised ear plugs, protective shoes with orthopedic inserts and protective glasses with corrective lenses, can be subjected to these production control because the tests will be performed on the primary model which is the subject of type examination and range adjustments would be defined.

4.3. Article 19 - The requirements for the designated body

Requirements for the designated body

Article 19

In order to be appointed to perform the conformity assessment activities referred to in this Rulebook, the conformity assessment body must meet the requirements of item. 1–10 of this article.

1) The conformity assessment body must have the status of a legal entity registered in the Republic of Serbia.

2) The conformity assessment body must be independent of all parties interested in the results of the conformity assessment ("third party") and independent of the organisation and PPE whose conformity it assesses.

A conformity assessment body that is a member of a business or professional association representing organisations involved in the design, manufacture, supply, assembly, use or maintenance of PPE whose conformity it assesses may be appointed provided it proves its independence and the absence of conflicts of interest.

3) Conformity assessment body, its director, ie members of the executive board of directors, executive directors or members of the supervisory board, etc. that body (hereinafter: top management), as well as employees and other persons engaged in the implementation of conformity assessment activities (hereinafter: staff) may not be designers, manufacturers, suppliers, customers, users or maintainers of PPE whose compliance is assessed, nor may they be representatives of either party.

This is without prejudice to the use of PPE that is necessary for the work of that body or the use of PPE for personal purposes.

The top management of the conformity assessment body, as well as its staff, must not be directly involved in the design, manufacture, delivery, use or maintenance of the PPE in question, nor be representative of any party involved in those activities.

They must not carry out activities that could affect their judgment and integrity in relation to the conformity assessment activities for which they have been appointed, in particular with regard to the provision of consulting services.

The conformity assessment body must ensure that the activities of its subcontractors do not endanger the confidentiality, objectivity and impartiality of the conduct of the conformity assessment activities.

4) The conformity assessment body and its staff shall carry out conformity assessment activities with the highest degree of professional integrity and with the necessary technical competence in a particular field and shall not be exposed to any pressures or other reasons and influences, especially financial, which could to influence the decision-making and the

results of the performed conformity assessment activities, especially by persons or groups of persons who are interested in the results of these activities.

5) The conformity assessment body must be competent to carry out the conformity assessment activities in accordance with the conformity assessment procedure for which it seeks designation, regardless of whether those activities are carried out by that body or under its responsibility.

For each type of PPE, as well as for each conformity assessment procedure for which the conformity assessment body requests the designation, that body, both before and after the designation, must have at its disposal:

(1) personnel with technical knowledge, as well as sufficient and appropriate experience to perform conformity assessment activities;

(2) descriptions of the procedures in accordance with which the conformity assessment is carried out, whereby transparency must be ensured, as well as ensuring that those procedures are applied in the same way. Also, the conformity assessment body must have and apply rules and procedures that clearly delineate the conformity assessment activities it carries out in its capacity as a notified body and the activities it carries out in another capacity or any other activity;

(3) procedures for performing conformity assessment activities that take into account the relevant aspects of the supplier's organisation and the PPE whose conformity is assessed, such as: size, activity and structure of the supplier, level of complexity of the PPE in question, mass or serial nature of the production process.

The conformity assessment body must have at its disposal all necessary means to enable it to perform, as appropriate, the technical and administrative tasks connected with the conformity assessment activities, and to have access to all necessary equipment or facilities.

6) Personnel in charge of performing conformity assessment activities must also have:

(1) appropriate professional and technical education and work experience, ie appropriate technical and professional training covering all conformity assessment activities in respect of which the body has been designated;

(2) adequate knowledge of the assessment requirements it conducts and the authority to perform those assessments;

(3) adequate knowledge and understanding of the essential requirements of Annex 2 to this Rulebook, relevant Serbian standards from the list of standards and relevant provisions of the law governing technical requirements for products and conformity assessment and regulations adopted pursuant to that law, in particular regulations compliance with harmonised European Union legislation;

(4) ability to prepare conformity documents, records and reports on performed conformity assessment activities in accordance with this Rulebook.

7) The impartiality of the conformity assessment body, ie its top management and staff carrying out conformity assessment activities, must be guaranteed. Salaries, allowances, or remuneration of personnel conducting conformity assessment activities must not depend on the number of assessments performed, nor on the results of such assessments.

8) The conformity assessment body must have concluded a contract on liability insurance for damage from professional activities.

9) The conformity assessment body and its staff must respect the confidentiality of data and information related to conformity assessment, in accordance with the law. This is without prejudice to the obligations of the conformity assessment body with the competent authorities. Property rights are protected in accordance with the law.

10) The conformity assessment body must participate in the relevant activities of standardisation organisations and group activities established to ensure coordination of designated and / or notified bodies, ie to ensure that its staff conducting conformity assessment activities are aware of the activities of those organisations and the group. The notified body shall, as a general rule, apply the guidelines and other acts of the groups for the coordination of the designated and / or notified bodies, in order to perform the work consistently and with equal quality and to carry out conformity assessment activities.

Article 19 of the Rulebook defines the criteria that designated bodies must meet. Bodies that can provide evidence of their compliance with these criteria submit to the Ministry of Economy the documents to prove eligibility for appointment.

It is believed that the bodies appointed for carrying out the assessment of compliance with the relevant health and safety requirements meet the requirements of the Rulebook and provide consistent technical implementation of these requirements in accordance with the procedures of the Rulebook . The designated body must have adequate premises and technical staff that allows them to perform the technical and administrative activities related to conformity assessment . They also must implement appropriate control procedures of quality of services rendered.

A notified body wishing to offer services in accordance with one or more of the conformity assessment procedures set out in Annexes 5, 7 and 8 must meet the relevant requirements for each procedure , which must also be assessed in accordance with these requirements. A notified body can be designated only for a defined range of products and may not be qualified to implement conformity assessment of all products covered by the Rulebook.

The designated bodies must have adequate procedures and processes to ensure that the conformity assessment and certification at any time can be monitored. Processes include responsibilities in relation to the requests to the producer to take corrective action and reporting to the competent authority.

Conformity assessment bodies must have a concluded contract on liability insurance for damage from professional activity. At the European level there is no recommendation that would suggest financial value of liability insurance. Generally it should match the level of activity of designated bodies in the PPE field.

In order to ensure technical competence, designated bodies are obliged to ensure that they are informed about standardisation and its development.

4.4. Article 20 - Assumption of fulfillment of the requirements for the notified body

Assumption of compliance with the requirements for the notified body

Article 20

It is presumed that the conformity assessment body, which proves the fulfillment of the requirements of the relevant Serbian standards or parts of those standards, also meets the

requirements of Article 19 of this Rulebook, to the extent that these requirements are covered by the said standards.

The relevant Serbian standards referred to in paragraph 1 of this Article are the Serbian standards which have taken over the relevant harmonised standards which contain the requirements for conformity assessment bodies.

The relevant harmonised standards, ie the EN ISO / IEC 17000 series of standards , provide useful and appropriate mechanisms for presuming compliance of notified bodies with some of the criteria set out in Article 19 of the Rulebook (these standards do not cover all these criteria). However, this does not exclude the possibility that the bodies are not in accordance with the harmonised standards to be appointed on the grounds that compliance is mandatory only in terms of the criteria set out in Article 19 of the Rulebook.

4.5. Article 21 - Requirements for the designated body in relation to its subcontractors

Requirements for the designated body in relation to its subcontractors

Article 21

The notified body may, with the agreement of the applicant for conformity assessment, subcontract, in the country or abroad, for the performance of certain conformity assessment activities for which that body has been designated. The notified body shall ensure that the subcontractor meets the requirements of Article 19 of this Ordinance and keeps evidence of this and makes it available to the appointing authority in accordance with the law governing the technical requirements for products and conformity assessment. The notified body shall retain responsibility for the work performed by the subcontractor. The appointed body shall be obliged to make available to the body responsible for appointment the relevant documentation relating to the competence of the subcontractor for the activities referred to in paragraph 1 of this Article.

In order to comply with the provisions of the Rulebook, the notified bodies must keep a register of all subcontractors and branches, in order to allow effective supervision. The notified body may engage experts to help implement assessment activities, but activities of the expert should be controlled just like that the expert is directly employed by the notified body under the same contractual obligations and operates within quality system of the designated body.

Although conformity assessment may be subcontracted, including the assessment of essential health and safety requirements, the designated body remains fully responsible for the whole work (for all activities) and protection of the impartiality and integrity.

5. CHAPTERV - CONTROL OVER PPE AND SAFEGUARD CLAUSE

Chapter 5 of the Rulebook deals with the control of the market, control of products entering the market and the safeguard clause.

A useful document for the authorities of market surveillance in the Member States is "Good practice for market surveillance", which was developed by experts of the market surveillance, which are members or chairman of various groups for administrative cooperation. The document is designed as a tool to aid in efficient cross-border supervision of markets

and ensure understanding the procedures set forth in the applicable m EU regulations that ensure a consistent approach to market surveillance.

In addition, the document contains checklists and other tools for performing market surveillance activities.

5.1. Article 22 - Procedures at the national level for working with PPE that pose a risk

Article 22

The competent supervisory authorities organise and conduct supervision over PPE in accordance with the law governing inspection supervision, ie the law governing technical requirements for products and conformity assessment and a special law.

The Supplier shall ensure that, without delay, all necessary corrective actions are taken to ensure that PPE delivered on the market and / or put into use, which is not compliant or there are reasons that the Supplier considers that it does not comply with the requirements of this Rulebook, these requests, withdrawn or, if necessary, recalled.

If the PPE delivered on the market and / or put into use represents a risk from the point of view of protection of public interest, ie does not comply with the requirements of this Rulebook, the supplier shall without delay submit a notification to the competent supervisory authority, corrective actions taken, in accordance with the law governing the technical requirements for products and conformity assessment, or a special law.

Corrective actions referred to in paragraph 2 of this Article shall be taken for all non-compliant PPE delivered on the market, in proportion to the risk posed by such PPE.

If a certificate of conformity has been issued for PPE referred to in paragraph 3 of this Article in accordance with this Rulebook, the designated body that issued that document shall be notified of the determined non-conformity.

If corrective actions have not been taken in accordance with paragraph 2 of this Article, appropriate measures shall be taken, in accordance with the law governing technical requirements for products and conformity assessment and a special law.

Where a product presents a risk at national level, a detailed procedure shall be established for the authorities of the Member States responsible for market surveillance in their territory, with specific obligations for the economic operators concerned , in order to manage the risk .

5.2. Article 23 - Safeguard clause

Safeguard clause

Article 23

Delivery or use of PPE delivered to the market and / or put into use, whose conformity has been assessed in accordance with this Rulebook, on which a mark of conformity has been affixed and for which a Declaration of Conformity has been made, accompanied by the prescribed documentation and used in in accordance with the intended purpose or in conditions that can be reasonably foreseen, and which is determined to pose a risk from the

aspect of protection of public interest covered by this Rulebook, may be limited or prohibited or that PPE may be withdrawn or recalled, in accordance with the laws regulate technical requirements for products and conformity assessment, market surveillance, safety and health at work and this Rulebook.

The safeguard clause provided in Article 23 of the Rulebook is a procedure that undertakes measures, on the basis of non-conformity with the essential health and safety requirements and when it is considered that PPE may endanger persons, animals or properties, for the purpose of withdrawing from the market, prohibiting the placing on the market or limiting free movement of PPE.

When considering whether a safeguard clause should be initiated, the competent authorities will consider whether non-conformity is a sufficient reason to initiate formal measures , or whether the problem of non-conformity can be resolved without safeguard procedures. For example, a slight discrepancy may be an illegible mark of conformity. In such cases, the producer or representative shall be instructed to take appropriate corrective measures.

5.3. Article 24 - Treatment of PPE that poses a risk

Treatment of PPE that poses a risk

Article 24

The competent supervisory authority, if there is sufficient reason to believe that the PPE poses a risk to human health and safety or to another aspect of the protection of the public interest, shall verify that the PPE meets the applicable requirements of this Rulebook.

The supplier is obliged to cooperate with the body referred to in paragraph 1 of this Article.

If, in performing the checks referred to in paragraph 1 of this Article, it is determined that the PPE does not comply with the prescribed requirements, the competent supervisory authority shall without delay order the supplier to take appropriate corrective actions to comply with those requirements, withdraw or recall the PPE within a reasonable time, decides in proportion to the risk posed by the PPE.

The competent supervisory authority shall notify the designated body that issued the certificate of conformity for the PPE in question of the determined non-compliance referred to in paragraph 3 of this Article, ie, when applicable, the competent authority that issued or recognised the certificate of conformity.

The supplier shall ensure that corrective actions referred to in paragraph 3 of this Article are taken for all PPE that he has delivered on the market, which has been determined to pose a risk. The competent supervisory authority shall take measures to prohibit or restrict the delivery, ie use of PPE, or its withdrawal or recall, if the supplier does not take corrective action within the period referred to in paragraph 3 of this Article.

The provisions on restrictive measures prescribed by a special law shall apply to the measures taken by the competent supervisory body in accordance with paragraph 6 of this Article.

5.4. Article 25 - Treatment of harmonised PPE which poses a risk

A special procedure is envisaged for PPE which is in line with the requirements of the Rulebook , but still poses a risk to health and safety. The competent state body is obliged

to take appropriate actions involving suppliers and to act in accordance with the Law on Market Surveillance ("Official Gazette of RS", No. 92/2011)

Dealing with a harmonised PPE that poses a risk

Article 25

When, following the procedure carried out in accordance with Article 24, paragraph 1 of this Rulebook, it is determined that PPE designed and manufactured in accordance with this Rulebook still poses a risk to human health or safety, the supplier shall take all appropriate action to ensure that the PPE in question is placed on the market, no longer poses a risk, as well as to withdraw it from the market or recall it within a reasonable time, in proportion to the nature of the risk.

The supplier shall ensure that corrective actions are taken for all PPE referred to in paragraph 1 of this Article that it has delivered on the market.

5.5. Article 26 - Formal non-conformity of PPE

Formal non-conformity of PPE

Article 26

A PPE is considered to be formally non-compliant if one of the following non-conformities is identified after delivery on the market:

1) affixing the mark of conformity contrary to the provisions of Article 16 of this Rulebook;

2) absence of the mark of conformity;

3) the absence of a unique number of the notified body that participated in the conformity assessment, or placing a unique number of the notified body contrary to the provisions of Article 16 of this Rulebook;

4) failure to make a declaration of conformity or incorrect drawing up of a declaration of conformity;

5) unavailability or incompleteness of technical documentation;

6) absence, incompleteness or inaccuracy of information referred to in Article 8, paragraph 7 and Article 10, paragraph 3 of this Rulebook;

7) failure to meet other requirements referred to in Article 8 or Article 10 of this Rulebook;

In case of non-elimination or recurrence of formal non-conformity, measures are taken in accordance with the law governing technical requirements for products and conformity assessment.

Formal non-conformity of PPE exists when it is not directly associated with the risk for health and safety, but it may be an indication of potential risks.

The cases referred to in Article 26 paragraph 1 include deficiencies in labeling, documentation and other information provided with PPE.

For example, the placement of labels and marks next to the mark of conformity is subject to certain restrictions. The authority of market surveillance must ensure that these principles are respected and if necessary take appropriate measures.

6. CHAPTER VI - TRANSITIONAL AND FINAL PROVISIONS

6.1. Article 27 - Marking of conformity by affixing the Serbian conformity mark

Article 27

From the day of application of this Rulebook until the day of entry into force of the ACAA agreement for PPE to which this Rulebook applies or, if that agreement is not concluded, until the day of accession of the Republic of Serbia to the European Union, by this rulebook and special regulations

6.2. Article 28 - Transitional provisions relating to the conformity assessment bodies and the validity of certificates of conformity

Article 28

Conformity assessment bodies designated in accordance with the regulation referred to in Article 29 of this Rulebook shall perform conformity assessment activities, in accordance with Article 18 of this Rulebook, until the completion of the designation procedure in accordance with this Rulebook.

The conformity assessment bodies referred to in paragraph 1 of this Article may submit a request for designation to the body responsible for designation in accordance with this Rulebook no later than six months from the day of its application.

Conformity assessment bodies referred to in paragraph 1 of this Article, which do not submit a request for appointment within the period referred to in paragraph 2 of this Article, or conformity assessment bodies for which the appointing authority, upon request, determines that they do not meet the requirements of this Rulebook , will not be able to perform conformity assessment activities as designated bodies in accordance with this Rulebook.

Certificates of conformity issued by the bodies referred to in paragraph 1 of this Article by the date of application of this Rulebook shall be valid until the expiration of the term for which they were issued, and documents of conformity issued by those bodies, based on the regulations referred to in Article 29. issued without a validity period, valid until April 21, 2023.

6.3. Articles 29 and 30 - Start of application

Article 29

The Rulebook on personal protective equipment ("Official Gazette of RS", No. 100/11) shall cease to be valid on the day of application of this Rulebook.

Article 30

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".

Given that the Rulebook transposes the Regulation on PPE (EU) 2016/425, which provides for a special transitional regime for PPE: a transitional period of one year (from 21 April 2018 to 20 April 2019) during which both the Directive and the Regulation on PPE and in accordance with Article 47, paragraph 1, PPE designed and manufactured in accordance with the PPE Directive 89/686/EEC can not be put on the market by 20 April 2019, in principle, EU certificates of examination type in accordance with PPE Directive may be issued until the end of the transitional period, ie. April 20, 201 9. For these products, in accordance with the Directive on PPE, it is not necessary to update the accompanying documentation (e.g. EU declarations of conformity) by April 20, 2019 . Since the Regulation on PPE applies from 21 April 2018, from that day producers can start placing PPE on the market in accordance with the Regulation.

Article 47, paragraph 2 provides that the EU certificates on examination of type and the approval decision issued under the PPE Directive before 21 April 2019 shall remain in force until 21 April 2023, unless they expire before that date.

7. ANNEX 1 - PPE categories according to risk

Annex 1

CATEGORIES OF PPE BY RISK

This annex determines the risk categories from which the PPE should protect the user.

Annex 1 deals with the categorisation of personal protective equipment (PPE) based on the type of risk. If PPE is intended to provide protection against multiple risks, they will be classified in the category corresponding to the risk or risks of the highest category .

Further in Appendix: Instructions for categorisation of personal protective equipment (PPE) , contain provision of PPE Rulebook on the categorisation of PPE according to the degree of risk the user is protected against

7.1. Category I

Annex 1 (continued)

Category I

Category I covers only the following minimum risks:

1) surface mechanical action;

2) contact with mild cleaning agents or prolonged contact with water;

3) contact with hot surfaces whose temperature does not exceed 50 ° C;

4) damage to the eyes due to exposure to sunlight (not during sun observation);

5) atmospheric influences that are not of an extreme nature

Superficial mechanical injuries are, for example, bruises, bites and scratches that appear when bumping into the fixed obstacles and do not require medical help.

Mild means for cleaning, for example surfactants diluted in water used for washing dishes, wherein the main risk may be atopic eczema due to a prolonged exposure to water and mild aqueous solutions, ie. when only waterproofing is necessary.

PPE for direct observation of the sun (eg solar eclipses) or against radiation from artificial light sources, such as those used in solariums, are PPE category II .

Atmospheric conditions that are not extreme in nature are normal weather conditions, ie. rain, spraying water and cold temperatures in winter, one can expect during the performance of activities in the open, for example, cleaning snow, sports activities, sailing and construction works.

7.2. Category II

Annex 1 (continued)

Category II

Category II covers all risks not listed in categories I and III;

7.3. Category III

Substances (1) and mixtures dangerous to health (carcinogenic, mutagenic, toxic , irritant or sensitive) include any liquid, gas or solid substance that poses a risk to human health and safety.

Biological agents (3) are microorganisms, including those that are genetically modified, cell cultures, and human endoparasites that may be able to cause infection, allergy, or toxicity. It is believed that biological agents, as well as multidrug-resistant bacteria, can cause very serious consequences, such as death or permanent damage to health .

Annex 1 (continued)

Category III

Category III covers risks that may cause death or serious and permanent damage to health from:

1) substances and mixtures that are dangerous to health;

2) atmosphere with lack of oxygen;

3) harmful biological agents;

4) ionizing radiation

5) environments with high temperature whose effect can be compared with the effect of air temperature of + 100 ° C or higher;

6) low temperature environments whose effects can be compared with the effect of air temperature of -50 ° C or lower;

7) falls from a height;

8) electric shock and live operation;

9) drowning;

10) cuts when working with a hand-held chainsaw;

11) high pressure jets;

12) gunshot wounds or stab wounds;

13) harmful noise.

(5) Risk of exposure to environments with high temperatures is associated with the effects comparable with air temperature of 100 ° C . It has been described in the scientific literature that exposure to air temperatures higher than 100 ° C , in combination with other aspects or risks, would lead to second degree injuries and burns in less than fifteen seconds. This means that the heat flux that is transferred to the skin will cause second-degree burns within fifteen seconds. This criterion for second degree burns should be considered as a criterion when deciding whether PPE which protects from heat is PPE of category III or not. This criterion should also be applied where there is a risk of splashing hot material and contact with hot surfaces.

The risk associated with exposure to low temperature environments (6) is associated with effects comparable to an air temperature of –50 ° C , the effects of a temperature of –50 ° C are seen in still air with a maximum wind speed of 5 km / h . These conditions can cause the exposed surface to freeze in less than two minutes. In conditions of higher wind speeds, this effect can be achieved at lower extreme temperatures. The conditions may result with frosting of stacked area in less than two minutes should be considered as criteria when deciding whether the PPE which protects against cold is PPE of category III or not.

Personal protective equipment for protection against falls from height (7) must be designed so as to prevent or stop the fall, as well as to support user in case of a fall. Examples are equipment used in roof work where there is a risk of falling to a lower level or climbing equipment used in rock climbing.

For PPE that provides protection against electric shock and live operation (8), voltages higher than 50 V AC or 75 V DC are usually considered dangerous and have very serious consequences, including cardiac arrest . Also included iis PPE dedicated to trained individuals, that is to be worn during work under voltage up to 800 kV AC and 600 kV DC.

PPE designed to prevent drowning (9) must be able to return the user to the surface as quickly as possible and without danger to health, and the user, who may be exhausted or unconscious after falling into a liquid medium, must be kept in water in a position that allows breathing until help arrives.

High pressure jets (11) require PPE to be designed and manufactured for protection when the operating pressure is 200 bar or more. According to the literature, the limit of penetration into the skin is 80 bar, but the usual work clothes provide protection up to 200 bar . Equipment with high pressure jets up to 3000 bar can be found on the market for professional use. Equipment used by consumers, such as high-pressure washing machines, has an operating pressure of less than 200 bar.

Personal protective equipment for protection against injuries caused by bullets and stab wounds (12) are, for example, safety vests, which protect against gunshot wounds and stab wounds.

8 ANNEX 2 - Important health and safety requirements

Essential health and safety requirements given in Annex 2 of the Rulebook are designed to ensure the highest possible level of protection. In practice, this means the best compromise between protection efficiency, usability and comfort in accordance with the generally accepted state of the art. These requirements are applied in accordance with the foreseeable conditions of use for which the PPE is dedicated. They either set possible protection objectives and / or relate to the performance of PPE .

The requirements define the results to be achieved or the risks to be addressed, but do not specify or envisage technical solutions that prescribe the manner of achieving them . They are also formulated to allow assessment of compliance with these requirements, in the absence of European harmonised standards or in the event that the producer decides not to apply them.

This flexibility allows producers to choose the most appropriate way to meet the requirements. It also allows, for example, to adapt materials and product design to technological progress. Consequently, harmonised regulations , such as the PPE Rulebook , do not require regular adaptation to technical progress, as the assessment of compliance with the requirements is based on technical knowledge at the time of assessment .

Annex II is divided into three parts:

- 1. general requirements for all PPE;
- 2 additional requirements common to more than one type or types of the PPE;
- 3. additional requirements specific for the particular risks.

Therefore , in addition to applying the general requirements, producers must clearly identify:

- the risk that the PPE is intended to protect in order to determine the additional requirements that will be applied to the PPE;
- foreseeable conditions of use for which PPE is intended for.

If the producer decides to use Serbian PPE standards which have adopted the relevant harmonised standards, the list of which is compiled and published in accordance with the law governing technical requirements for products and conformity assessment in the procedure for assessing compliance with the Rulebook , they will ensure that these standards include all requirements (EHSRs) that are applicable to their PPE under the foreseeable conditions of use for which the PPE is dedicated. If existing standards do not include all valid requirement for health and safety , the producer will , with use of these standards, evaluate compliance with the requirements which are not covered , and the use of other relevant technical specifications and test methods.

The requirements set out in Annex 2 include everything necessary to comply with the requirements of the Rulebook . PPE can be put on the market only if it complies with all applicable requirements for health and safety and conditions of this Rulebook .

8.1. Introductory notes

In order to ensure that the production provided by PPE is adequate to the risk, the producer should perform PPE risk assessment in order to identify the intended use and the required level of protection under reasonably foreseeable use.

ANNEX 2 (continued)

INTRODUCTORY REMARKS

The application of the essential health and safety requirements of this Annex is mandatory.

Obligations relating to essential health and safety requirements apply only if there is an appropriate risk from which the PPE in question should protect.

The essential health and safety requirements are applied in such a way as to take into account the latest developments and existing practices at the time of design and production, as well as technical and economic requirements corresponding to a high level of health and safety protection.

The manufacturer conducts a risk assessment to identify the risks related to the PPE it produces.

When designing and manufacturing the manufacturer takes into account the assessment made.

When designing and manufacturing PPE, and when preparing the instructions, the manufacturer, in addition to the intended purpose of PPE, also takes into account the use that can be reasonably foreseen.

Where applicable, the health and safety of non-users must be ensured.

The introductory note reminds that the requirements (EHSRs) , when applicable to a certain type of PPE , are legally binding. This is clearly seen in Article 8 (1) which sets out the obligations of producers. In this regard, it is important to distinguish between requirements (EHSRs) in Annex 2 of specification of harmonised European standards which are implemented voluntarily.

It must be borne in mind when reading each request (EHSRs) from Annex 2 that the requests are applicable only when they are relevant and necessary .

The term "latest achievement" is not defined as such in the Rulebook . However, it is clear from the introductory note that the notion of "latest developments" includes both technical and economic aspects. In order to meet the "*latest developments*", technical solutions adopted to meet the requirements (EHSRs) must use the most effective technical means available at the time at a price that is reasonable.

Perhaps it is not always possible to fully meet certain requirements (EHSRs) , given the current "latest developments". In such cases, the producer of PPE must try to meet the objectives set by the requirements as much as possible.

PPE producers cannot be expected to use solutions that are still in the research phase or technical means that are generally not available on the market. On the other hand, they must take into account technical progress and adopt the most efficient technical solutions that are most appropriate for the PPE in question when they become available at a reasonable cost.

Harmonised European standards are usually taken as a reference for defining "latest developments" at a given time.

The term "risk assessment" is used to assess various risks. The risk assessment in the Rulebook must not be confused with the risk assessment that the employer is obliged to conduct in connection with the Law on Safety and Health at Work ("Official Gazette of RS", No. 101/05, 91/15 and 113/17) . The risk assessment in the Rulebook is related only to PPE

and not to the conditions of work or use. On one hand, the producer must assess which risks the PPE they produce should protect against. On the other hand, the producer must assess the risks associated with the use of the produced PPE under foreseeable conditions of use.

The results of the risk assessment should be reflected in the technical documentation, as well as in the instructions and information of the producer so that the user can assess the risk reduction when using PPE (quantitatively or qualitatively) under foreseeable conditions of use. Instructions and producer information to be separated include: the maximum value of the exposed grains to harmful agents of which PPE provide protection (if applicable), the maximum time secur s (if applicable), the environmental conditions, which affect the efficiency of the PPE (e.g., moisture , temperature), restrictions on use, identification of signs of loss of protective function PPE.

The producer must take into account the reasonably foreseeable use of PPE. The producer of PPE cannot be expected to take into account all possible uses of PPE. However, of a particular type of use, whether intentional or unintentional , they are predictable based on experiences of previous uses of the same type of PPE or similar L PPE , based on accident investigations and knowledge of human behavior.

8.2. General requirements for all PPE (1)

ANNEX 2 (continued)

1. GENERAL REQUIREMENTS FOR ALL PPE

PPE must provide adequate protection against all possible risks, in accordance with the intended purpose.

The new Rulebook transfers focus of protection that PPE should provide from the " protection against all risks encountered " to " protection against the risk which the PPE is intended to protect against " .

8.3. Principles of design

ANNEX 2 (continued)

1.1. Design principles

1.1.1. Ergonomics

PPE must be designed and constructed so that in the conditions of the intended purpose, the user can perform the activity without hindrance and have the highest possible level of protection.

In PPE project phase it is necessary to apply ergonomic principles to PPE adapt its protective function under the foreseeable conditions of use.

Operational requirements for PPE must be simultaneously assessed on the basis of the levels:

- protection that must be at the highest possible level according to the latest achievements ;

- maximum reasonable "usability" so that it adapts to the characteristics and environment in which the tasks are performed by potentially different users.

ANNEX 2 (continued)

1.1.2. Protection levels and classes

1.1.2.1. The highest possible level of protection

The optimal level of protection that must be taken into account in the design is the one above which restrictions on the use of PPE would prevent its effective use during risk exposure or normal performance of activities.

This requirement introduces the principle of the best possible balance between the highest possible level of protection and the lowest possible degree of restriction (see also point 1.1.1 of Annex 2) However, for very specific applications, user safety takes precedence. This is especially the case when, according to the latest achievements, it is not possible to provide comfort and protection from high levels of danger at the same time (eg rescue during an emergency, protection against ionizing radiation , removal of landmines ...).

Performance tests in practice with the help of respondents can be reported in order to assess the acceptability of PPE and the feasibility of the planned activity.

ANNEX 2

1.1.2.2. Protection classes appropriate to different levels of risk

When several levels of the same risk can be distinguished under different conditions of use of PPE, the appropriate protection classes must be taken into account in the design.

It is easier to indicate the nature of the risk than to quantify its level. In practice, protection classes are generally defined by the performance levels of one or more characteristics. These performance levels are determined by conventional testing methods that simulate risk situations as realistically as possible .

The number of classes should be kept to a minimum in order to avoid difficulties and mistakes during the selection phase of the appropriate PPE by users and customers. In fact, the creation of several classes of protection can only be justified by the existence of many different fields of application, in terms of risk levels and ergonomic factors, which can include one class of PPE.

On the other hand, a different class of protection may be useful when they offer , where possible, use more comfortable PPE instead of PPE with unnecessarilyhigh level of protection.

In any case, if several protection classes and/ or performance levels are used , the appropriate risk levels and / or fields of application must be clearly identified and stated in the producer's instructions and information.

Furthermore, when defining classes of protection, to see also in the standards or other specifications, it should take into account the measuring uncertainty of the result of a test in order to avoid difficulties in interpretation.

8.4.Non-harmfulness of PPE

ANNEX 2 (continued)

1.2. Harmlessness of PPE

1.2.1. Absence of risk and other harmful factors

PPE must be designed and constructed in such a way as to prevent risks and other harmful factors under the intended conditions of use.

Even if possible causes of damage are eliminated during the design of PPE , as much as possible, the use of PPE can sometimes cause damage to the user. This is especially true if the selected PPE is not optimal or is used incorrectly or in inappropriate working situations. Therefore, the requirements and guidelines for proper selection and use should be carefully considered. Ergonomic, physiological and other factors should be taken into account.

These additional risks are not related to the risks they protect against.

The following examples illustrate the additional risks that PPE can create :

- tight PPE that prevents sweat from evaporating and causes, for example, hyperthermia, skin irritation, and discomfort;
- " Pockets " in PPE existence of which allows contact with hot or cold products;
- PPE which leads to difficulties in recognizing optical or audible warning signals;
- psycho-physiological limitations such as increased metabolic rate or fatigue.

ANNEX 2 (continued)

1.2.1.1. Materials suitable for making PPE

Materials and parts of PPE, including the products of their decomposition, must not adversely affect the hygiene or health of users.

The constituent materials in predictable conditions of normal use can not release or break down to release the substances which are known to be toxic, carcinogenic, mutagenic, allergens, teratogenic or otherwise harmful.

The following are examples of possible documents that can be used to demonstrate compliance with this requirement:

a) A statement made by the producer confirming that PPE does not contain any substances at levels known or suspected to adversely affect the hygiene or health of users;

b) Material specifications;

c) Safety data sheets relating to materials;

d) information relating to the suitability of the material for use with food, in medical devices or other relevant applications;

e) test reports or other information relating to toxicological, allergenic, carcinogenic, toxic to reproduction or mutagenic tests and measurements on materials;

f) Information related to ecotoxicological and other studies of the impact of materials on the environment .

Special attention should be paid to the presence of plasticizers, unreacted components, heavy metals, impurities and chemical identity of pigments and paints.

Limits for exposure to harmful substances, such as, for example, Cr (VI), Ni and azo – colours are often specified in European or national regulations.

In particular, the producer should take into account:

1. Law on Chemicals ("Official Gazette of RS", No. 36/09, 88/10, 92/11, 93/12 and 25/15);
2. Rulebook on restrictions and prohibitions of production, placing on the market and use of chemicals (" Official Gazette of RS ", No. 90/13, 25/15, 2/16, 44/17, 36/18 and 9/20);
3. Rulebook on the manner in which the chemical safety assessment is performed and the content of the chemical safety report (" Official Gazette of RS ", No. 37/11);
4. Rulebook on the criteria for the identification of the substance as PBT or vPvB (" Official Gazette of RS ", No. , 23 / 10);
5. Rulebook on the content of the safety data sheet (" Official Gazette of RS ", No. 100/11);
6. List of substances of concern (" Official Gazette of RS ", No. 94/13, 101/16 and 22/18);
7. List of candidate substances for the List of substances of concern (" Official Gazette of RS ", No. 58/16 and 22/18);
8. Rulebook on methods of testing hazardous properties of chemicals (" Official Gazette of RS ", No. 117/13);
9. Rulebook on the Register of Chemicals (" Official Gazette of RS ", No. 16/16, 6/17, 117/17, 44/18 - other laws , 7/19 and 93/19) .
10 . Rulebook on classification, packaging, labeling and advertising of chemicals and certain products in accordance with the Globally Harmonised System for Classification and Labeling of the UN (" Official Gazette of RS ", No. 105/13, 52/17, and 21/19) ;
11 . Rules on the List of Classified Substances (" Off. Gazette of RS ", No. 22 / 20) .

These regulations, among other requirements assume Regulations (EC) No. 1272/2008 (CLP) on the classification, labeling and packaging the substance or mixture and Regulations (EC) no.1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). This Regulation also applies to PPE which may contain hazardous chemicals that come into direct and prolonged contact with the skin.

ANNEX 2 (continued)

1.2.1.2. Surface properties of PPE parts that may be in contact with the user

The surface of any part of the PPE that is or may be in contact with the user during wearing must not be rough, with sharp edges, protrusions or such as to cause excessive irritation or injury.

Evaluation of roughness characteristics , sharp edges, etc. that can cause injury can be based on objective tests (e.g., visual or tactile), and / or on practical experience. For example, the attachment elements of the helmet that pass through the shell of the helmet must not be placed in a way that poses a risk to the user.

Injuries can arise not only from the characteristics of PPE, but also from the activities of users.

ANNEX 2 (continued)

1.2.1.3. Maximum allowable interference to the user

Any restriction in movement, in taking the appropriate body position and sensory perception when using PPE must be minimised. In addition, the use of PPE must not cause movements that could endanger the user.

Obstacle to movement in particular depends on the weight and dimensions PPE , which must take into account not only the morphology of the user who it is intended for , but also the dynamics of movement that demands their activity, customization options and features of the constituent materials. For example, the thicker and stiffer the constituent materials , the more likely they are to impede movement.

Disruption of the user's sensory perception can take many forms. For example , hearing protectors are intended to provide attenuation of noise reaching the intended user's ears , but this requirement should also be considered in conjunction with the user's need to communicate with other operators and / or to hear warning signals.

Another example is fire-fighting clothing that should provide protection from heat and flame. Protection may be lower for a smaller part of the body so that the intended user becomes more aware of the danger and avoids it .

In terms of sensory perception, it is necessary to look for the best possible relationship between safety and usability. For example, the glove should preserve the dexterity and tactile sensitivity of the intended holder, while still providing protection against risks that may be mechanical, chemical and / or thermal.

In order to assess the compliance of PPE with the requirements, objective test methods for measuring the physical characteristics that affect the user can be used , such as size, stiffness, weight, field of view, etc. When there is no objective method for measuring the level of restraint of movement , subjective tests can be performed through practical test on the persons performing tasks that simulate the possible foreseeable conditions of use.

8.5. Comfortability and efficiency

ANNEX 2 (continued)

1.3. Comfort and efficiency

PPE must be designed and constructed so as to provide the maximum possible comfort and efficiency for each user, thus for different morphology types and for both genders.

ANNEX 2 (continued)

1.3.1. Customization of PPE to the user

PPE must be designed and constructed in such a way as to facilitate proper placement on the user and to remain in place during the intended period of use, taking into account environmental factors, the movements to be made and the positions of the body.

The PPE must be able to adapt to the user using appropriate adjustment and fastening systems or an appropriate size range.

Many elements must be taken into account in order to describe the morphology, ie. to define the shapes of the human body. Where possible , it is useful to
use PPE adaptation systems for each holder in order to avoid the production of individual user-friendly products, the production of which is not cost-effective.

PPE must be equipped with elements which ensure that the continuous functional PPE , taking into account all possible foreseeable factors, such as the forces that affect the stability of PPE , movements to be made and postures that will be occupied during the tasks, etc.

For example:

- Protective helmets need to be stable on the head of the holder: equal weighing allocation, the corresponding center of gravity location and a belt at the back are several ways to achieve this goal . If necessary, and acceptable from the standpoint of security , the helmet could be equipped also with chin belt.
- Life jackets must remain in place when the user falls into water.

PPE must be designed and constructed in such a way as to facilitate proper installation on the user. Testing the respondents or laboratory measurements can also be used for assessment of objective criteria:

- Adaptability , adaptability stability;
- Consequences of displacement PPE and maximum displacement tolerated ;
- Static and dynamic forces that can affect PPE in normal use and in circumstances where the intended protection .

ANNEX 2 (continued)

1.3.2. Lightness and strength of PPE

PPE must be as light as possible, without compromising strength and efficiency.

In addition to the additional essential requirements for special risks referred to in point 3 of this Annex, the PPE must be able to withstand the impacts and phenomena inherent in the intended conditions of use.

The producer is obliged to design the PPE so as to achieve the most favorable compromise between weight and protection efficiency. PPE can have detrimental effects on the body by increasing muscle strain or energy expenditure by increased or altered passive or dynamic load . Weight (and its distribution) of PPE must be taken into account in relation to a particular part or parts of the body that may be affected. For example, the extra weight on the head produces pressure on the neck muscles, which can negatively affect the health and safety of the user. Heavy weights on the body or parts of the body increase energy consumption, especially when walking or running .

The effectiveness of PPE can be influenced by a number of environmental factors . These factors can reduce the effectiveness of protection over time. The producer is obliged to provide sufficient information on how environmental factors affect the level of protection and how the user can estimate the lifespan of PPE. The producer is obliged to include in the instructions for use the predictable environment and working conditions that they took into account when designing the PPE in order to enable proper use and selection.

PPE must remain safe for use and must not lead to dangerous situations in case of malfunction, damage or errors in the logic of the circuit.

ANNEX 2 (continued)

1.3.3. Compatibility of different classes and types of PPE designed for simultaneous use

If the same manufacturer places on the market several PPE models of different types or types in order to ensure the simultaneous protection of adjacent parts of the user's body from combined risks, these models must be compatible.

When it is envisaged that different types of PPE from the same producer are worn at the same time, the producer is obliged to ensure that the safety function and comfort of each PPE are not endangered by wearing another PPE. For example, ear protectors or face shields are considered compatible with the protection helmet if safety features and comfort of hearing protector and face shield are not impaired by simultaneously carrying of the PPE.

In all cases, the producer is also obliged to drawthe attention of users to any restriction of use or possible incompatibility.

Any protective clothing with means for the installation of replaceable protectors should provide a protective function: therefore, such clothing is PPE. Protective clothing with explicit means for the installation of replaceable guards must, in conformity assessment procedures , be assessed in combination with the replaceable shields intended for installation . This protective clothing must be accompanied by explicit information for end users on the characteristics of the corresponding interchangeable shield in combination with which they are assessed.

ANNEX 2 (continued)

1.3.4. Protective clothing with replaceable guards

Protective clothing with replaceable protectors is PPE and is assessed as a combination during the conformity assessment procedure.

In case the replaceable shields are placed on the market, they are required to be certified as PPE because they must meet all applicable requirements of the Rulebook (Declaration of conformity, a mark of conformity , etc.).

8.6. Information provided by the producer

ANNEX 2 (continued)

1.4. Information provided by the manufacturer

In addition to the business name or the name and address of the manufacturer's registered office and / or his representative, the manufacturer, when placing PPE on the market, in the Serbian language, provides precise and understandable written information on:

The producer's instructions and information are a basic element of PPE and are considered an integral part of PPE. They must be clear, concise and understandable, giving appropriate information to the intended user.

The producer's instructions and information provide the user with a basis for a reasoned choice of the appropriate PPE for the intended activity.

When assessing the type, conformity assessment body also makes assessment of producer’s instructions and information in terms of content and understanding. The conformity assessment body checks if claims of the producer about the field and boundaries of protection of the

product in accordance with the used technical specifications and the relevant essential safety requirements in order to determine whether PPE can be safely used for their intended purpose.

The producer's instructions and information must comply with the essential health and safety requirements , but also, if necessary, with other applicable essential requirements .

The producer is obliged to provide instructions and information with each unit of PPE that is placed on the market, in paper form or as a print on the packaging. For some types of PPE, such as earplugs or specific protective gloves that are sometimes sold in boxes , instructions for use may be placed on the boxes or supplied with each unit.

ANNEX 2, 1.4. (continued)

(1) storage, use, cleaning, maintenance, servicing and disinfection. The cleaning, maintenance or disinfection products recommended by the manufacturer must not have a negative effect on PPE or users when used in accordance with the relevant instructions;

Storage instructions must specify the conditions, for example the method of storage, maximum temperature of use, cleaning procedures, etc.

The producer's instructions and information must provide the necessary information regarding the insertion or removal of the PPE as well as instructions and information on adaptation to the user's morphology.

The producer may not waive the obligation to define cleaning (including decontamination when necessary), maintenance and, if applicable, disinfection procedures , as these are necessary to ensure the hygiene of PPE users .

Instructions for cleaning, maintenance and disinfection must specify the products or at least the criteria for their selection, as well as procedures that need to be implemented. These procedures should specify :

- preliminary actions such as the dismantling of sensitive components, types and concentrations of cleaning agents ;
- washing conditions, ie. domestic and / or industrial process of washing and temperature ;
- conditions of drying, i.e. m ethods and temperatures;
- the highest number of washings which a can be carried out , i.e. for how many washes PPE was examined ;
- actions necessary after washing or maintenance, to ensure that PPE maintains an optimal level of efficiency. For example, cleaning procedures include drying conditions for PPE intended for protection against heat and flame or precautions to be taken in relation to electric shock if the PPE has electrical or electronic components.

The condition and disinfection depends on the type of PPE and the way the user wears it. They can be less restrictive if there is no direct contact of PPE to the user's skin, for example, belts to the system for preventing falls. On the other hand, they should be very detailed if there is, for example, direct and prolonged contact with the skin, as is the case with respiratory protective devices or protective gloves.

Maintenance instructions must specify which actions the user can perform himself, how to perform them and which spare parts to use , for example which filters can be used in the face mask and how to replace them; or on repairing holes, seams and replacing zippers , etc. It is also necessary to state when the intervention of the producer or expert is needed.

Any product specified by the producer for the cleaning, maintenance or disinfection of PPE must not be harmful to the PPE or the user. For example, the recommended products should be tested for carcinogenic or allergic reactions and should not destroy the integrity of the material used in PPE. Adverse effects on the user can be confirmed by the use of product safety data sheets , while effects on the integrity of PPE can be checked by applying the cleaning procedure according to the producer's instructions before performing the PPE performance test .

ANNEX 2, 1.4. (continued)

(2) the performance recorded during the technical tests to verify the level or class of protection provided by the tested PPE;

The data shall indicate the levels or classes of protection specified by the producer in accordance with the standards or other relevant specifications . The information shall be based on a risk assessment in accordance with Annex 2, which is included in the technical documentation described in Annex 3 to the Rulebook .

The producer must specify in his instructions and data the accessories and spare parts compatible with PPE. The producer is responsible for the design of these accessories and their compatibility with PPE. The producer is not responsible if anyone uses accessories other than those provided for .

ANNEX 2, 1.4. (continued)

(3) appropriate PPE accessories and characteristics of appropriate spare parts;

(4) protection classes appropriate to different levels of risk and on appropriate restrictions on use;

The producer's instructions and information must provide the necessary information on the replacement of accessories and spare parts and restrictions on their use.

For the protection class specified by the producer, the instructions must specify the level of risk covered and the corresponding restrictions on use . They mainly express:

- the nature of the risk covered ;
- restrictions on the parameters that define the risk (temperature, pressure, sound level, list of chemicals, etc.);
- time limit of risk exposure.

These levels of covered risk are sometimes difficult to know in advance. In such cases, they may be indicated by reference to the test conditions in which the EU type- examination was performed .

ANNEX 2, 1.4. (continued)

(5) the shelf life or shelf life of the PPE or any of its components;

Obsolescence information can be expressed in different ways to indicate that PPE is no longer usable , for example:

- expiration date regardless of the time of use;
- time of use: e.g. hours after opening the packaging, maximum number of re- use ofvPPE, individual or limited use, etc .;
- as a function of incident: impact (belt after fall, helmet after impact), in case of contamination :

• defects such as holes, cracks, etc. because of which should PPE should be fixed.

Information about the obsolescence of the information about when PPE becomes useless for their purpose, or is no longer suitable for this purpose because of change of protective properties or loss of functionality within the stipulated period or after a longer use, so the user has information on whether to reject or repair PPE .

The producer is obliged to provide all necessary information so that the user can determine a reasonable period of obsolescence. However, the producer is not obliged to set the date of manufacture on the product or in its instructions and information if the obsolescence of PPE does not depend on the date of manufacture, however there are other factors such as the estimated number of uses or performance after certain cleaning cycles , etc.

Lifetime of PPE depends on many factors such as storage conditions, use, cleaning, revision, maintenance, over which producer has no control. The producer is obliged to provide all useful information in order for the user to determine a reasonable time limit. This may be a matter of developing a characteristic of use (e.g., increased respiratory resistance, making it difficult to use), or a characteristic of aspect and / or integrity (e.g., a striped or split eyepiece). It can also refer to material fatigue. For example, the appearance of cracks or fading of the surface of some types of thermoplastic protective helmet can be an objective sign of aging.

ANNEX 2, 1.4. (continued)

(6) the type of packaging suitable for transport;

This refers to the description of the packaging, which users should use for transportation, for example, the original packaging or special packaging, in order to maintain security and usability features of PPE or PPE protection when not in use .

Request from point 2.12. refers to the labels of PPE that directly or indirectly relates to the health or safety of users. There are other provisions in the Rulebook that mention the placement of labels with special significance, for example the essential requirements (EHSRs) in point 2.4 . (relating to PPE susceptible to aging), 3.5 . (which refers to the equipment for the protection of hearing a), 3.9 . (relating to the protection of the eyes from ionizing radiation), 3.10 . (refers to respiratory protection devices).

ANNEX 2, 1.4. (continued)

(7) the meaning of all markings (in accordance with item 2.12 of this Annex);

In addition to these mandatory labelings, there may be other labels or

ANNEX 2, 1.4. (continued)

(8) the risk from which the PPE should protect;

pictograms, which provide useful information on the area of use of PPE and their level of performance. This must be clearly explained in the instructions for use and must not lead to confusion regarding mandatory labeling, ie. mark of conformity .

Producer in their instructions and information clearly informs the user on the intended use of PPE and risks the protection is envisaged against based on a risk assessment which is carried out in accordance with Annex 2 " Opening Remarks" which is included in the technical documentation referred to in Annex 3 of the Rulebook.

This requirement applies only to the application of regulations relating to the affixing of a mark of conformity . The rules listed here are, for example, for medical devices or other gas appliances, which the producer has applied to PPE.

ANNEX 2, 1.4. (continued)

(9) a reference to this Rulebook and, where appropriate, to other applicable regulations;

This requirement applies only to PPE of categories II and III . For PPE category III also the name, address and identification number of the body for the assessment of conformity which is involved in the evaluation process conformity to module C2 or module D . It can be the same body or two different ones.

Using the body for conformity assessment in the evaluation of conformity does not release the producer from their obligations as specified in the relevant articles of the Rulebook .

ANNEX 2, 1.4. (continued)

(10) the business name or title, address and unique number of the notified body that participated in the PPE conformity assessment procedure;

ANNEX 2, 1.4. (continued)

(11) reference to the applicable Serbian standards or other technical specifications when applied;

This includes the title of the standard and the year of publication as published in the Official Gazette to ensure the presumption of conformity . This is necessary to provide clear and not ambiguous information to users on the version of the standard in force .

In the event that the selected option is Internet, different solutions can be used (eg. direct web address, a generic web page with search function), but it must be clearly explained how these would lead to reaching Declaration on conformity that refers to a particular PPE . The Internet connection will be maintained during the working life of the PPE .

ANNEX 2, 1.4. (continued)

(12) the internet address where the declaration of conformity is available.

Since this information is part of Declaration of conformity, it is not necessary to repeat information if the Declaration of compliance submitted together with PPE.

ANNEX 2, 1.4. (continued)

Information from sub-items. (9) - (12) items 1.4. of this annex do not have to be in the manufacturer's instructions, if the PPE is accompanied by a declaration of conformity.

8.7. Additional requirements common to several types or types of PPE (2)

8.8. PPE with built-in adjustment systems

By the correct project, the producer will ensure that no inadvertent changes

ANNEX 2 (continued)

2. ADDITIONAL REQUIREMENTS COMMON TO MULTIPLE SPECIES OR TYPES

2.1. PPE with built-in adjustment systems

If the PPE has built-in adjustment systems, these systems must be designed and constructed in such a way that the settings are not disturbed without the user's knowledge under the intended conditions of use.

of settings can affect the level of protection afforded by PPE. For example, the adjustment of the length of the straps of the whole body connection system must not be changed during use when the tension in the belts and buckles differs.

This condition is generally met for binders if they are unavailable during task performance. When the binder components are available, an accidental release must not be possible, for example. when two simultaneous voluntary performances of different movements are required.

8.9. PPE that completely covers the parts of the body that need to be protected

ANNEX 2 (continued)

2.2. PPE that completely covers the parts of the body that need to be protected

PPE that completely covers the parts of the body to be protected must be sufficiently air permeable to prevent excessive sweating during use, and if this is not the case, it must be equipped with means that absorb sweat.

The main method that the body uses to maintain the proper temperature is to evaporate sweat. It is obvious that PPE affects this physiological phenomenon in users.

As a result, PPE must be designed so that it induces a minimal sweating, in order to enable a sufficient level of ventilation in accordance with the task and foreseeable conditions of use, or for production of PPE transparent materials which allow the exchange of gases must be used. In order to increase comfort, for example where protection from a toxic environment is required and where PPE must be impermeable, sweat-absorbing materials are chosen.

Where the essential requirements for health and safety are applied , the producer in the instructions and information must specify the necessary level of needed speed of ventilation if PPE is supplied with air ventilation. Useful maintenance information must also be provided by specifying the cleaning and drying to be performed after use.

8.10. PPE for face, eyes and respiratory system

ANNEX 2 (continued)

2.3. PPE for face, eyes and respiratory system

PPE for the face, eyes or respiratory system must be such as to limit as little as possible the field of vision or visual acuity of the user.

The degree of optical neutrality of the vision system of these types of PPE must be such as to enable the user to work accurately and for a long time.

If necessary, PPE must be treated or equipped to prevent condensation.

PPE models intended for users who need vision correction must be able to wear glasses or contact lenses.

Any limitation of the user's natural field of vision must be kept to a minimum in order to minimise the risks or inconveniences associated with the planned tasks or environment.

PPE for eye protection must not reduce the field of vision to ensure user comfort and must have the lowest possible refractive power to be optically neutral . PPE for eye protection with low refractive power is recommended for continuous use or for careful work.

Lenses with a protective layer against fogging must be designed so that these characteristics prevent the formation of moisture in all foreseeable conditions and the use for which the PPE is intended . Information on how to clean the anti-fog lens to avoid damaging the coating must be described in the operating instructions.

Devices integrated in PPE for reducing moisture must be designed to prevent fogging without reducing the level of protection of PPE , e.g. ventilation holes of the glasses.

The air flow in the integrated air ventilation must not create harmful effects or disturbances on health (noise ...).

In order to determine the dimensions of the PPE intended for installation over corrective glasses, the producer takes into account the normal dimensions of the glasses.

If possible, it is advisable to integrate optical correction into the PPE or provide an appropriate holder to support corrective glasses .

8.11. PPE susceptible to ageing

ANNEX 2 (continued)

2.4. PPE susceptible to ageing

If the projected performance of a new PPE is known to be significantly affected by ageing, the date of manufacture and / or, if possible, the shelf life of the PPE, it must be indelibly marked on each PPE sample or on each replaceable PPE component placed on the market. in such a way as to prevent any misinterpretation. This information must be indelibly marked on the packaging.

If the manufacturer is unable to provide information on the shelf life of PPE, his instructions must provide all the information necessary to enable the customer or user to determine a reasonable shelf life, taking into account the quality of the model and satisfactory storage, use, cleaning, servicing and maintenance conditions.

If the cleaning procedures recommended by the manufacturer may lead to ageing and a significant and rapid deterioration in PPE performance, the manufacturer must, where possible, affix to each copy of PPE placed on the market a sign indicating how much cleaning can be done before inspecting or disposing of equipment. If it fails to do so, the manufacturer must provide this information in the accompanying documentation.

Factors of ageing, time, environment and use all affect the performance of PPE. In technical documentation the producer should define the conditions environment as well as the anticipated conditions of use to be taken into account when assessing the impact of ageing on the PPE. It is understood that the expiry date of the PPE corresponds to a reduction of the protective performance to a level that is not adequate in relation to the risk.

The producer is obliged to ensure that the characteristics of PPE do not change significantly during storage.

The expiration date of the PPE, i.e. lifespan PPE is under the influence of the conditions of use of PPE and its interconnected by a exchangeable components . The shelf life can be expressed over time or as a number of exposures. It is not possible for the producer to have complete control over the conditions of use, therefore the producer provides the PPE user with all relevant information on the intended conditions of use and all other factors affecting the lifespan if the user can determine when to reject the PPE.

If the prescribed cleaning procedure leads to a rapid and significant deterioration in the performance of PPE, the maximum number of cleanings that can be performed should be stated in the markings and instructions for use.

For example:

- Certain protective clothing has a top coat that will withstand only a few washes, but can be renewed according to the instructions for use. In this case, specified maximum number is the number of cleanings between the renewal of finishing layer , or the maximum amount of re-treatments.
- Certain materials used in protective clothing or gloves do not suffer from cleaning. In that case, the PPE is marked that the product is intended for a single use .

8.12. PPE that may be affected by another object during use

ANNEX 2 (continued)

2.5. PPE that may be affected by another facility during use

Where the intended conditions of use include in particular the risk of the PPE being affected by moving objects creating a hazard to the user, the PPE must have an appropriate resistance threshold above which the component breaks and eliminates the hazard.

PPE must be designed so that there is no risk of it being affected by another object. If the risk of the PPE being affected by some other object can not be prevented, PPE must be designed so that this component has a corresponding threshold of resistance to breakage in order to avoid injury. Breakage resistance depends on the characteristics of the contact of PPE components and their assembly. PPE must be designed taking into account the characteristics of the parts of the body that can be injured, as well as the severity of the injury. For example, a chin helmet strap for small children must be released to prevent strangling if the helmet is caught while playing.

The risk of PPE being affected by another object can be avoided by design requirements , e.g. for clothes. If the risk of catching PPE by another movable object cannot be prevented, the producer's instructions and information will clearly warn that this PPE is not used in situations where this risk exists.

8.13. PPE for use in a potentially explosive atmosphere

ANNEX 2 (continued)

2.6. PPE for use in a potentially explosive atmosphere

PPE intended for use in a potentially explosive atmosphere must be designed and constructed in such a way that it cannot be a source of electric, electrostatic or shock-induced arc or spark that could ignite the explosive mixture.

PPE for use in potentially explosive atmospheres, should :

- have antistatic properties that are active throughout the working life when used and maintained properly , in accordance with the instructions and information of the producer;
- be made of materials that are known not to cause sparks , e.g. in a collision ;
- strictly avoid the use of PPE components that can cause sparks due to impact or friction;
- not include unprotected electrical components or parts that do not comply (where relevant) with the Rulebook on equipment and protective systems intended for use in potentially explosive atmospheres ("Official Gazette of RS", No. 10/17 (ATEX);
- provide adequate warning in the instructions for use;
- take into account other relevant factors in foreseen use

Equipment covered by the Rulebook is exclusively excluded from ATEX Rulebook and will be marked with a special mark of protection against explosion defined in that Rulebook .

8.14. PPE intended for use in emergencies or for quick installation and / or removal

ANNEX 2 (continued)

2.7. PPE intended for emergency use or for quick installation and / or removal

PPE intended for emergency use or for rapid installation and / or removal must be designed and constructed in such a way as to minimise the time required for their installation and / or removal.

All component systems that allow the correct installation or removal of PPE from the user must allow the user to handle them quickly and easily.

The ease of installation and removal of PPE intended for use in emergencies must be as good as possible, taking into account foreseeable emergencies and the duration of tasks. The verification of the required time can be performed only by using the examinees in realistically simulated conditions.

In some cases, it is important to remove the PPE quickly in order to avoid or limit serious injuries: e.g. when hot or cold particles or liquid accidentally enter the PPE . In other cases, other criteria should also be considered, such as in the case of protection against chemical or biological contamination.

The instructions for use contain information on quick installation or removal of PPE and tips for proper user training.

8.15. PPE for use in very dangerous situations

ANNEX 2 (continued)

2.8. PPE for use in very dangerous situations

PPE for use in very hazardous situations must contain, in particular, manufacturer's information intended exclusively for trained and trained individuals who are qualified to interpret it and provide the user with the correct use of such PPE.

The data referred to in paragraph 1 of this item, among other things, must describe the procedure applied in order to confirm that the PPE is correctly set up and to function when worn by the user.

If the PPE has an alarm that is activated in the absence of the prescribed level of protection, that alarm must be so designed and located that the user can observe it in the conditions for which the PPE is intended.

PPE intended for this type of task belongs to category III .

If the producer considers that PPE can only be used by trained persons, additional information should be provided, such as:

- details of training of "trainers" of future users;
- Proper setting up and adjusting of PPE to increase efficiency;
- correct procedure for verification of PPE functionality (e.g. with content and periodicity of controls).

The warning device integrated in the PPE must be designed to remain effective, e.g. visible and / or audible, in all foreseeable conditions of use and regardless of the anticipated variations of the environment (e.g. heat, cold, humidity, electromagnetic radiation, shocks). This alarm device, in addition to other relevant factors, must take into account the following:

- sound environment;
- wearing hearing protection (see condition 3.5);
- ambient lighting;
- use in colored optical radiation filters.

When the producer considers that the required level of protection cannot be provided, even with a warning device, it is necessary to include the warning in the instructions for use, e.g. by adding information on environments in which PPE should not be used .

8.16. PPE containing components that the user can adjust or remove

ANNEX 2 (continued)

2.9. PPE containing components that the user can adjust or remove

All PPE components that the user can adjust or remove for replacement must be designed and constructed to facilitate their adjustment, fastening and removal without tools.

The instructions provided by the producer shall specify the adjustment and replacement that can be made by the user without tools (eg. changing filters with standard thread for devices

for respiratory protection) and those who that should be performed by a trained person only (eg. maintenance of devices to stop falls). In the first case it is necessary to include procedures that should be followed for safe and easy adjustment and replacement without tools, in the instructions for use.

Settings that can be made without tools are limited to a safe area. For example, it is not possible to completely shut off the air supply to the constant flow valve in compressed air breathing apparatus.

8.17. PPE for connection, i.e. connection to other, external additional devices

ANNEX 2 (continued)

2.10. PPE for connection, ie connection to other, external additional devices

If the PPE includes a system that allows connection, ie connection to another, external accessory, the connection mechanism must be designed and constructed in such a way as to allow it to be mounted only on appropriate equipment.

As much as possible, PPE should be designed to prevent misconnection. Accordingly, information provided by the producer must describe how to ensure a secure connection and , if necessary, give appropriate warnings.

If PPE designed so that the outer complementary PPE equipment can be connected, for example, in different conditions of use, the information provided by the producer must provide an exhaustive list of these external complementary equipment PPE and instructions on how to correctly use.

For example, if PPE must be connected with the inlet of gas mixtures which can be inhalated, connector should be designed so that it is impossible to connect to the gas supply which is not inhalated, such as a nitrogen circle.

8.18. PPE with built-in fluid circulation system

ANNEX 2 (continued)

2.11. PPE with built-in fluid circulation system

If the PPE includes a fluid circulation system, it must be selected, ie designed and installed in such a way as to enable the recovery of fluid in the vicinity of the entire body part being protected, regardless of the movements and position of the user's body under the intended conditions of use.

The most common use of these systems is in hot or cold environments or in situations where the user must be completely isolated from polluted atmospheres and it is necessary to maintain body temperature within acceptable limits.

Used pipes should have sufficiently high mechanical resistance to collapse under mechanical pressure. The effectiveness of the system of circulation should be designed in accordance with the terms of the environment and the metabolic rate of the user in order to provide thermal comfort or to prevent excessive thermal load for the user.

8.19. PPE with one or more identification marks or identification marks that are directly or indirectly related to health and safety

ANNEX 2 (continued)

2.12. PPE with one or more identification marks or identification marks that are directly or indirectly related to health and safety

Identification or recognition marks that are directly or indirectly related to health and safety and that are placed on these types or types of PPE should preferably be in the form of harmonised pictograms or ideograms and must remain perfectly legible during the intended lifespan of the PPE.

The markings referred to in paragraph 1 of this item must be complete, precise and understandable in order to prevent any misinterpretation.

When the markings from para. 1 and 2 of this item contain words or sentences, they must be in the Serbian language.

If the PPE (or PPE components) is too small for all or part of the necessary markings to be affixed to it, the relevant information must be stated on the packaging and in the manufacturer's instructions for the use of the PPE.

Labels must not create confusion in relation to the covered risk or category of PPE. The information provided by the producer must state the exact meaning of any pictogram (see requirement 1.4 item 7). These markings shall be designed so that remain legible during the lifetime of PPE, which means that the labels affixed on PPE can not be easily removed and / or damaged by, for example, scratching, cleaning or exposing to the sun.

Labels can only be considered effective when they are complete, accurate and understandable and when the end user notices, understands and applies them .

For the use of harmonised pictograms or ideograms, the producer may refer to ISO 7000: 2019 Graphical symbols for use on equipment - Registered symbols (Graphical symbols for use on equipment) .

8.20. PPE in the form of clothing that visibly indicates the presence of users

ANNEX 2 (continued)

2.13. PPE in the form of clothing that visibly indicates the presence of users

PPE in the form of clothing intended for predictable conditions of use, in which the presence of the user must be clearly and individually visible, must have one (or more) adequately placed means or device for emitting direct or reflective visible radiation of appropriate light intensity and photometric and colorimetric properties.

The aim of this requirement is to make the user of PPE visible especially during movement in the area where motor vehicles or other mobile machines are moving , especially when the lighting is dim. Compliance with this requirement enables better identification of PPE users by the driver, but does not protect users of the PPE from the risk of collision. The form of direct signaling or reflective material attached to the PPE must enable the driver to recognise that it is a person and not a fixed obstacle. Signaling or materials must be placed so that in the

foreseeable conditions of use for which the PPE is intended , signaling surfaces are not obstructed.

8.21. PPE intended for protection against multiple risks

ANNEX 2 (continued)

2.14. PPE intended for protection against multiple risks

All PPE designed to protect users from multiple potentially simultaneous risks must be designed and constructed to meet, above all, the essential protection requirements specific to each of those risks (in accordance with point 3 of this Annex).

A full-face respiratory protection device simultaneously protects against inhalation of substances and mixtures that are dangerous to health, and the face and eyes from splashing chemicals. In addition, it must not unnecessarily restrict the field of vision, and the optical quality of the visor must be such as not to impair vision.

Certain types of protective clothing protect against several risks at the same time. For example, protective clothing for welders working in the traffic environment , outside in the darkness and the cold must protect against sparks, to be visible and protect against harmful environmental factors.

8.22. Additional requirements specific for the particular risks (3)

ANNEX 2 (continued)

3. ADDITIONAL REQUIREMENTS SPECIFIC TO CERTAIN RISKS

8.23. Protection against mechanical shocks

ANNEX 2 (continued)

3.1. Protection against mechanical shocks

3.1.1. Impact caused by falling objects or projectiles and collision of body parts with an obstacle

PPE suitable for protection against this type of risk must have the ability to absorb shock in order to prevent injury due to crushing or penetration of the protected part of the body, at least to the level of impact above which excessive dimensions or weight of the part of shock absorbing equipment would prevent efficient use. PPE in the intended period of carrying.

Impact tolerance criteria for different body parts are derived from a combination of accidents and consequences data .

The impact of a shock is not only related to its energy level, but also to other parameters such as the direction of the shock. The optimal level of protection should be taken into account in the design phase.

8.24. Falls

ANNEX 2 (continued)

3.1.2. Falls

3.1.2.1. Prevention of falls due to slipping

Anti-slip soles must be designed, constructed or fitted with additional elements in such a way as to ensure satisfactory grip with regard to the nature or condition of the surface.

There are several factors that affect the risk of slipping. One of the most important factors that affects the friction of the soles of shoes. The friction of the sole on the walking surface must be within the appropriate range of friction values . The properties of the walking surfaces that correspond to the foreseeable conditions for which the PPE is intended will be taken into account during the design. Properties of friction of soles made of certain materials may also differ depending on the temperature or during lifetime.

For footwear used on slippery icy surfaces, the producer may design footwear with spikes or similar additional elements. The producer can also design a specific removable PPE that can be easily, firmly and securely attached to footwear.

ANNEX 2 (continued)

3.1.2.2. Preventing falls from heights

PPE intended to prevent falls from a height or their consequences must be designed to prevent a fall from a height or its consequences by including body straps and a fastening system which can be connected to a reliable external anchorage.

The PPE must be designed so that, under foreseeable conditions of use, the vertical fall of the user is mitigated, to prevent collisions with obstacles, and the braking force does not reach the limit value at which a part of the PPE can be expected to be injured, torn or broken. could cause a drop in users.

The PPE referred to in paragraph 1 of this item must also ensure that after braking the user is kept in the correct position in which he can expect help, if necessary.

The manufacturer's instructions must specify in particular all relevant information relating to:

1) the required characteristics required for a reliable anchorage and the necessary minimum free space under the user;

2) the correct way of placing the straps on the body and connecting the fastening system to a reliable anchor.

PPE for the prevention of falls from a height must be designed and in such a way that:

- the user is prevented from reaching any dangerous area where there is a risk of free fall (restraint equipment); or
- If the risk of a similar circumferential fall can not be prevented, PPE must prevent collision with obstacles or the ground and have a braking force that is not harmful for the user to reduce the risk of injury, for example. by directing the force of the shock to stronger parts of the body or by using devices that absorb energy.

All components of fall protection systems and assemblies must comply with the Rulebook . The producer is obliged to state in the instructions for use which components can be used together and how to assemble them correctly.

PPE must be designed so that the victim, in the event of an accident, can wait for help in the correct position without excessive harmful effects .

8.25. Mechanical vibrations

ANNEX 2 (continued)

3.1.3. Mechanical vibrations

PPE designed to prevent the action of mechanical vibrations must provide adequate damping of harmful vibrations for the part of the body at risk.

The Rulebook on Preventive Measures for Safe and Healthy Work during Vibration Exposure ("Official Gazette of RS", No. 93/11 and 86/19) on the exposure of workers to risks arising from physical agents contains provisions aimed at avoiding or reducing the risk that arises due to vibration.

8.26. Protection against static compression of the body

ANNEX 2 (continued)

3.2. Protection against static compression of body parts

PPE designed to protect the part of the body from static pressure that causes compression must provide sufficient mitigation of the effects of that pressure to prevent serious injury or chronic discomfort to the user.

8.27. Protection against mechanical injuries

ANNEX 2 (continued)

3.3. Protection against mechanical injuries

Materials that are part of PPE and other PPE components designed to protect all or part of the body from surface injuries caused by machinery, such as abrasions, punctures, cuts or pinches, must be selected and integrated, as well as designed to ensure that this PPE be sufficiently resistant to wear, puncture and cutting (in accordance with item 3.1 of this Annex) under foreseeable conditions of use.

Resistance to wearing out, puncture and incision are important properties for many PPE , because the risks are present in most tasks. In most cases, they are caused by:

- wearing out : contact with abrasive surfaces or abrasive products, sanding;
- punching : contact with sharp pointed objects;
- notching : contact with sharp or jagged edges.

8.28. Protection in liquids

ANNEX 2 (continued)

3.4. Protection in liquids

3.4.1. Drowning protection

PPE designed to prevent drowning must ensure that the user, who may be exhausted or unconscious after falling into a liquid, returns to the surface as quickly as possible without danger to health and must keep him on the surface in a position that allows breathing while waiting. help.

PPE may have full or partial buoyancy or may be inflated, by mouth blowing or by gas released manually or automatically.

Under the intended conditions of use:

1) PPE must withstand the consequences of the influence of the liquid medium and the environmental factors inherent in that medium, without diminishing its usability;

2) PPE on inflatable must enable fast and complete inflating.

When the intended conditions of use require it, certain types of PPE must meet one or more of the following additional requirements:

1) they must have all the inflating devices specified in the second indent of this paragraph and / or a light or sound signaling device;

2) they must have a device for hanging and fastening the body, so that the user can get up from the liquid;

3) they must be suitable for prolonged use during activities in which the user (and in the case of clothing) is exposed to the risk of falling into a liquid or immersion.

PPE that meets this requirement protects the user from the risk of drowning and belongs to the PPE category III . In general, "liquid medium" is considered to refer to water.

Buoyancy aids and lifejackets that people on airplanes and ships do not carry permanently are not the subject to Rulebook (see Section 2), but other specific regulations.

This type of PPE must protect against drowning even if the user is unconscious . Therefore, the inflation time of the inflating device should be as short as possible in order to save (especially) the injured or unconscious person.

Light or sound signaling devices listed in the request must be visible to rescuers in all foreseeable conditions of use for which the PPE is intended. Reflecting materials must be effective also when they are wet .

For prolonged use where there is a risk of falling into the water, ergonomic requirements, such as comfort and usability during activities, must be taken into account .

ANNEX 2 (continued)

3.4.2. Buoyancy aids

Buoyancy aids are considered to be PPE in the form of clothing which, depending on its intended use, will provide an effective degree of buoyancy and which is safe to wear and provides maintenance on the water.

Under foreseeable conditions of use, the clothing referred to in paragraph 1 of this item must not restrict the user's freedom of movement, but must enable him, in particular, to swim, escape from danger or save other persons.

Over the years, the boundary between different types of buoyancy aids has been debated . The general understanding is as follows :

- swimming bracelets are PPE category II which provide only assistance in floating;
- floating seats are covered by the Law on General Product Safety ("Official Gazette of RS", No. 41/09 and 77/19) ;
- inflatable means are toys, in the sense of the Rulebook on safety of toys ("Official Gazette of RS", No. 78/19) and the Law on items of general use ("Official Gazette of RS", No. 25/19) , when in shallow water is used by children under 14 years of age. In other cases, they are covered by the Law on General Product Safety ("Official Gazette of RS", No. 41/09 and 77/19) .

Buoyancy aids allow the unconscious user to remain on the surface of the water , but do not necessarily keep the head out of the liquid medium. PPE for protection against drowning keeps the head out of the liquid medium but may offer reduced mobility.

8.29. Protection against the harmful effects of noise

ANNEX 2 (continued)

3.5. Protection against the harmful effects of noise

PPE designed to prevent the harmful effects of noise must dampen the noise to the extent that the equivalent noise level to which the user is exposed does not exceed under any circumstances the daily limit value set by a special regulation governing the protection of employees from risks related to noise exposure at work.

All PPE must have a label indicating the level of noise attenuation and the value of the protection index provided by the PPE, and if this is not possible, the label must be affixed to the packaging.

Predicted attenuation can be obtained by passive (ear muffs , earplugs or a combination) or active hearing protection (depending on the level, active reduction or means of communication).

Communication systems located in some hearing protectors must be designed so that they do not exceed the limits of exposure to harmful noise.

The ability to understand speech or listen to warning signals should be considered when designing hearing protectors for specific applications.

For some users, such as musicians, it is important to hear sound of different frequencies correctly, so hearing protectors must have sound attenuation characteristics that encompass all frequencies.

If the earplugs are made to measure, the producer will perform tests on the prototypes and provide information in the instructions for use , for a professional, on how to properly shape these earplugs. The conformity assessment body conducts tests and checks the instructions for use.

The packaging of the hearing protector should be marked with noise attenuation levels so that the user can choose the most appropriate protector.

8.30. Heat and/or fire protection

ANNEX 2 (continued)

3.6. Heat and / or fire protection

PPE designed to protect the whole body or part of the body from the effects of heat and / or fire must have the ability of thermal insulation and mechanical strength appropriate to the foreseeable conditions of use.

This type of PPE consists of several layers of protective material or one, sufficiently thick layer, with a thermal insulation capacity necessary to achieve the required protection . The effectiveness of protection depends not only on the insulation capacity, but also on the correct insulation coverage. PPE must be designed so that heat or flame cannot harm the user through possible openings and so that protection against heat and flame is not reduced during exposure . Therefore, sufficient mechanical strength is necessary, e.g. against wearing out, cutting and tearing.

ANNEX 2 (continued)

3.6.1. Materials that are part of PPE and other components

Materials that are part of PPE and other components for protection against thermal radiation and convective heat must have an appropriate coefficient of heat transfer and heat action and be non-flammable enough to prevent any risk of spontaneous combustion under predictable conditions of use.

If the exterior of the material referred to in paragraph 1 of this item must be reflective, the reflectance must be appropriate to the intensity of the heat transferred due to radiation in the infrared range.

The materials referred to in paragraph 1 of this item are intended for short-term use in a high temperature environment and PPE that may be exposed to spraying with hot products, such as large quantities of molten material, except for the characteristics referred to in para. 1 and 2 of this point, must have sufficient thermal capacity to retain most of the received heat until the user leaves the dangerous place and removes his PPE.

Materials that are part of PPE and other components that can be sprayed with a large amount of hot things, must also have the appropriate ability to absorb mechanical shocks (in accordance with paragraph 3.1. Of this annex).

Materials that are part of PPE and other components that may accidentally come into contact with the flame and those used in the manufacture of firefighting equipment must have non-

flammability that corresponds to the risk class associated with the foreseeable conditions of use. These materials must not melt when exposed to flame or contribute to the spread of flame.

The request refers to the constituent materials and components, and not to the complete PPE.

The mechanical resistance of PPE, materials and other components must provide the user with sufficient protection against the impact energy, nature and temperature of the hot spray.

The producer must select materials, components or combinations thereof so that under foreseeable conditions of use:

- heat flux (heat transfer) transferred to the skin of the user will not cause burns ;
- flammability and / or melting do not create an additional risk of burns for the user.

The reflective capacity of the materials used in the design of the PPE should be as high as possible without increasing other harmful factors such as heat load due to the impermeability of clothing materials.

The heat capacity of materials, combinations of materials or components to be used in high temperature environments must be designed so that the user after exposure has enough time to leave a dangerous place and remove PPE before the heat accumulated in the materials cause any damage.

ANNEX 2 (continued)

3.6.2. Fully completed PPE ready for use

Under foreseeable conditions of use:

1) During the wearing of PPE, the accumulated heat transferred to the affected part of the body must be low enough to prevent reaching the threshold of pain or damage to the health of the user, in any circumstances;

2) PPE must, if necessary, prevent the ingress of liquid or vapor and must not cause burns caused by contact between its protective cover and the user.

If the PPE includes cooling devices that absorb heat through liquid evaporation or sublimation, their construction must be such that the volatile substances are released outside the outer protective layer, and not towards the user.

If the PPE includes a breathing apparatus, it must adequately perform the protective functions for the foreseeable conditions of use.

The manufacturer's instructions accompanying each PPE intended for short-term use in a high temperature environment must contain all relevant data for determining the maximum permissible exposure of the user to heat transferred through the equipment when used in accordance with its intended purpose.

If, in a foreseeable and intended use, there is a risk that the user of the PPE may encounter an electric arc, protection against the heat resulting from such an incident must be provided.

For an intended use , the producer must design the PPE so that :

- heat accumulation by PPE does not cause heat load , pain or harmful effects for the user;

- it prevents any penetration of liquids or vapors that may cause burns, e.g. proper coverage of body parts to be protected;
- parts PPE that can reach harmful temperatures are not in direct contact with the user.

Personal protective equipment, which includes devices for cooling, which absorb heat , must be designed so that volatiles are released away from the user so as not to cause any additional harmful in the foreseeable conditions of use.

PPE that protects against heat and includes a respiratory device must be designed to meet the essential health and safety requirements applicable to respiratory protective devices: e.g. the flow of air in from the principles of the ventilation must be as high as to protect against excessive heat and inhalation of polluted air .

For PPE for short-term use at high temperatures, the producer must provide information on the maximum effective protection time and / or the maximum acceptable use time from a physiological point of view so that the user can determine the protection during his planned actions.

8.31. Cold protection

ANNEX 2 (continued)

3.7. Cold protection

PPE designed to protect the whole body or part of it from the effects of cold must have the ability of thermal insulation and mechanical strength appropriate to the foreseeable conditions of use.

PPE for protection against cold is designed according to the anticipated risks and usually consists of several layers of protective material . The protection efficiency of this type of PPE depends on the insulation capacities and the appropriate coverage. The size and model of the PPE must be such that the cold does not harm the user through possible openings in the PPE.

PPE of this type must also have adequate mechanical strength against wearing out, cutting and tearing .

ANNEX 2 (continued)

3.7.1. Materials from which PPE and other components are made

The materials from which the PPE is made and other components suitable for protection against cold must have a sufficiently low coefficient of heat flux transfer required for predictable conditions of use.

Flexible materials and other PPE components intended for use at low temperatures must retain the degree of flexibility required for the necessary movements and body positions.

The materials from which the PPE is made and other components that can be flooded with a large amount of cold substances must have sufficient ability to absorb mechanical shock (in accordance with item 3.1 of this Annex).

This requirement applies to constituent materials and components and not to complete PPE.

The producer must select materials, components or a combination thereof so that under foreseeable conditions of use:

- the heat flux transmitted through PPE is as low as possible;
- flexibility remains acceptable so as to ensure the comfort , usability and integrity of the product.

The mechanical resistance of the component material must , where necessary, be appropriate to the impact energy, nature and spray temperature of the cold substances .

ANNEX 2 (continued)

3.7.2. Fully completed PPE ready for use

Under foreseeable conditions of use:

1) The amount of heat lost by the use of PPE by the user must be small enough to prevent reaching the pain threshold or damage to health on any part of the body, including the fingertips and toes, under any circumstances.

2) PPE must prevent the penetration of liquids such as rain as much as possible and must not cause injuries due to contact between the cold protective cover and the user.

If the PPE includes a breathing apparatus, it must adequately fulfill the protective functions for the foreseeable conditions of use.

The manufacturer's instructions, which accompany each sample of PPE intended for short-term use in a low temperature environment, must contain all relevant information on the maximum permissible exposure of the user to the cold transmitted through the equipment.

The producer must design the PPE such that in consideration live conditions of use for which the PPE is intended:

- loss of body heat does not cause hypothermia, pain or harmful effects, especially on the extremities of the user (eg fingertips and toes);
- prevents the penetration of liquids, such as rain , which are likely to cause injuries, e.g. proper coverage of body parts to be protected;
- parts of the PPE that can reach harmful cold temperatures must not be in direct contact with the user.

Personal protective equipment against cold, which includes a breathing apparatus, must be designed to meet the requirement applicable to respiratory protective devices : e.g. that the temperature of the air flowing in is physiologically acceptable.

With regard to PPE for short use in cold environments, the producer must provide information on the maximum effective duration of protection and / or the maximum acceptable time of use from a physiological point of view so that the user can determine protection during his planned actions.

8.32. Electric shock protection

ANNEX 2 (continued)

3.8.1. Insulation equipment

PPE designed to protect the whole body or part of it from the effects of electricity must provide sufficient insulation from the voltage to which the user may be exposed under the most adverse conditions.

In order to achieve the protection referred to in paragraph 1 of this item, the materials of which PPE and other components of these classes of PPE are made must be selected, designed and installed to ensure that the electric current penetrating through the protective sheath is measured under matching test conditions. with those that are likely to appear in the field, be reduced and always below the maximum allowable value.

Certain types of PPE that are intended exclusively for use during operation of electrical installations that are or may be live, as well as their packaging, must bear markings indicating the protection class or the corresponding operating voltage, serial number and date of manufacture. Outside the protective cover of such PPE, space must be provided for the subsequent entry of the date of commencement of use and the date of the periodic tests or inspections to be carried out.

The manufacturer's instructions must indicate the exclusive purpose of the PPE referred to in paragraph 3 of this item, as well as the nature and frequency of the dielectric tests to which they will be exposed during their service life.

To identify "the least favourable forseeable conditions" , the producer will need to consider:

- the risk of direct contact with a conductor under voltage ;
- possible harmful electric parametres and limits;
- skin moisture;
- the effect of contact with the used chemicals such as solvent and , the effect of mechanical degradation / aging and climate factors to environmental compartments during normal use of PPE.

Labeling the protection classes on PPE for professional use, intended for protection against electric shock, is necessary in order to provide traceability, information about the extent of use and the necessary periodic checks .

In addition to electric shock, it is necessary to take into account other risks associated with short circuits, such as thermal and mechanical risks.

The producer must clearly indicate the following in the instructions for use :

- the maximum voltage for the class in question ;
- condition is stored;
- controls to be carried out , visual inspection and inspection of the permeability of the gloves as well as a period of re-inspection and, usually before each use;
- maintenance of PPE.

In addition , precautionary measures should be mentioned, especially aimed at preserving the characteristics of the electrical insulation PPE or at protection against deterioration, e.g. using " covering gloves " to reduce the risk of bites, wearing out , cuts and chemical attacks.

ANNEX 2 (continued)

3.8.2. Conductive equipment

PPE intended for operation under high voltage must be designed and constructed in such a way as to ensure that there is no potential difference between the user and the installations on which he works.

The request refers only to the conductive PPE intended to be carried by professionals during work on systems of nominal supply voltage up to 800 kV AC and 600 kV DC .

Conductive clothing has a very low electrical resistance and is used to create electrical protection for users when working with very high voltage elements . The producer's instructions and information should include information that the continuity between different garments cannot be interrupted and information that guarantees the same resistance throughout the body.

Conductive equipment, ie. electrostatic dissipative protective equipment of surface resistance to $10^{3}\Omega$, is used as part of the overall system ground for avoiding accidental discharge (static- a) and treated is in Annex 2 of the Rulebook .

8.33. Protection against radiation

ANNEX 2 (continued)

3.9. Radiation protection

3.9.1. Non-ionizing radiation

PPE designed to protect against acute or chronic eye damage caused by non-ionizing radiation must be able to absorb or reflect most of the energy radiated in the range of harmful wavelengths, without interfering with the transmission of the visible part of the spectrum, contrast perception and color discrimination under predictable conditions. use.

In order to achieve the protection referred to in paragraph 1 of this item, safety glasses must be designed and manufactured so that for each harmful wavelength they have a spectral transmission factor that will minimise the energy density of light radiation that reaches the user's eye through the filter, does not exceed the maximum allowable exposure values.

In addition to the requirements of paragraph 2 of this item, spectacles must not deteriorate or lose their characteristics as a result of radiation emitted under foreseeable conditions of use, and all specimens on the market must have a protection factor number corresponding to the spectral distribution chart of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in ascending order of their number of protection factor, and the manufacturer's instructions should indicate, in particular, the method of selecting the most appropriate PPE, taking into account factors of real conditions of use such as source distance and spectral energy distribution. radiation at that distance.

The manufacturer must mark all specimens of filter goggles with the appropriate protection factor number.

When designing PPE to protect the eyes and skin from non-ionizing radiation, the producer will have to take into account the following:

- spectral and additional characteristics of radiation sources;
- for eye protection, ambient lighting;
- distance of the carrier from the source ;
- for eye protection, the need to enable color recognition (eg with warning lights or material identification at elevated temperatures);

- influence of radiation and friction on the efficiency of exposed PPE, e.g. sun, UV, IR radiation or laser beams. The transmission characteristics of PPE remain at the required level during the lifetime of PPE;
- updated exposure limit values;

When this requirement refers to "radiation sources of the same type", it refers, for example, to those of the same nature (eg infrared radiation) or to the same type of operations (eg radiation produced by arc and gas welding stations and related process).

The producer must provide information on the scale or shade numbers of the PPE and the replaceable spare parts and the corresponding field of use via the information labels on the PPE and in the instructions for use. When the PPE forms a single unit with irreplaceable filters (e.g. laser eye shields), markings can be placed on the frame.

Equipment that protects the skin from non-ionizing radiation is considered PPE if the producer guarantees protection against erythema.

Equipment that protects against natural UV radiation is considered PPE if it is designed and manufactured to have specific properties of protection against UV radiation.

Creams that protect against natural UV radiation, ie. k reme for protection from the Sun, are not PPE in accordance with the Regulations .

ANNEX 2 (continued)

3.9.2. Ionizing radiation

3.9.2.1. Protection against external radioactive contamination

The materials of which PPE and other components are designed to protect the whole body or part thereof from radioactive dust, gases, liquids or mixtures thereof must be so selected or designed and assembled as to ensure that this equipment effectively prevents the penetration of contaminants under foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary sealing may be provided by impermeable protective sheaths and / or any other suitable means, such as ventilation and overpressure systems designed to prevent the re-spreading (re-spreading) of these contaminants.

All decontamination measures applied to PPE must not endanger its possible re-use during the foreseeable period of use of these classes of equipment.

The producer's instructions and information must specify the decontamination procedure , applicable only to reusable PPE , which PPE can withstand without significantly deteriorating the level of protection.

PPE for protection against external radiation is the final solution in case of deterioration of the characteristics of the shelter . Equivalent to the thickness of lead is given according to this restrictive energy so that the user is not exposed via gra zero treshold value exposure.

ANNEX 2 (continued)

3.9.2.2. Protection against external radiation

PPE intended to provide complete protection of users from external radiation or, at least, their attenuation, must be designed to stop the radiation of low-energy electrons (eg beta) or photons (eg X, gamma).

The materials from which the PPE and other components of the PPE type referred to in paragraph 1 of this item are made must be selected or designed and installed in such a way as to provide the level of user protection required under foreseeable conditions of use and not to increase the duration of exposure due to movement, position or movement of the user (in accordance with item 1.3.2 of this Annex).

The PPE must have a sign indicating that the type and thickness of the material from which the PPE is made is suitable for the foreseeable conditions of use.

Lead and heavy metals are only used to soften X- or gamma- rays. In the case of beta radiation, the use of this type of protection should be avoided because it heavy metals will stop beta radiation, but also cause a brake ventilation , which is called " Bremsstrahlung ". There is no special protection against beta radiation other than equipment made of elastomer or polymer that helps to stop some of the radiation. The degree of protection depends on the material, its thickness and radiation energy.

The degree of protection offered by PPE is characterised by the determination of the equivalent thickness of the lead plate with the same rate of attenuation of ionizing radiation. If PPE contains several components, each component and their assembly offer the required level of protection regardless of the position occupied by the user.

The thickness in question can be expressed as the equivalent thickness of lead. The aim is to provide useful information to the user on the attenuation of ionizing radiation offered by PPE.

The equivalent thickness of lead must always be given with the radiant energy at which it was verified.

8.34. The protection system of hazardous substances and infectious agents

ANNEX 2 (continued)

3.10. Protection against hazardous substances and infectious agents

3.10.1. Respiratory protection

PPE intended for respiratory protection must allow the user to be supplied with respiratory air when exposed to a polluted atmosphere and / or low oxygen concentration.

Breathing air supplied to the user via PPE must be obtained in an appropriate manner, such as filtration of polluted air, through a protective device or by pipelines from an external unpolluted source.

The materials from which PPE and other components of these types of PPE from paragraph 1 of this item are made must be selected or designed and installed in such a way as to ensure proper breathing of the user and respiratory hygiene during the given period of wearing in predictable conditions of use.

The impermeability of the cheek and the drop in inhalation pressure and, in the case of filtration devices, the purification capacity, must be such as to sufficiently prevent the penetration of pollutants from the atmosphere so as not to endanger the health and hygiene of the user.

The PPE referred to in paragraph 1 of this item must have an appropriate label to identify the manufacturer and must be provided with precise specific data of that type of equipment which, together with instructions for use, enable a trained and qualified user to use this PPE correctly.

The manufacturer's instructions must, in the case of filtering apparatus, contain the shelf life of the filter if it is new and in its original packaging.

It is advisable to design PPE so that exposure to substances and mixtures that are dangerous to health and harmful biological agents clearly below the required limits. The air supply must have the appropriate temperature and humidity so that it does not affect the user's comfort, does not cause harmful effects and does not endanger the safe operation of the PPE.

Minimum concentration of oxygen in the air to which is inhaled must be sufficient , taking into account the requirements of user tasks. The amount of exhaled air that is re-inhaled must be kept to a minimum to avoid the accumulation of carbon dioxide inside the face mask . For very short periods of use, for example for evacuation devices, higher concentrations of carbon dioxide can be accepted.

The filtration efficiency of substances and mixtures that are dangerous to health and harmful biological agents depends on the size, distribution and nature of aerosols, particles, gases and vapors, as well as on the characteristics of the filter elements. Changes in filtration efficiency must be taken into account when designing the device and adequate instructions must be given.

The supply of breathing gas in compressed air or oxygen breathing apparatus should be provided by the proper design of the mechanical, manpower and function. The risks caused by the wrong combination of the air supply system of the breathing apparatus must be eliminated by design as much as possible . If this is not possible, the producer shall provide appropriate information on safe combinations.

The respiratory protective device must not contain or release any substances known to be harmful. All materials used should be listed in the user information. The release of harmful filter material from the filter must be eliminated.

The producer is obliged to label all respiratory protective devices, their components and important spare parts, so that it is clear to which device they belong. These markings must also be described in the instructions for use.

All filters must be labelled with appropriate pictograms and information on the shelf life of the filter when stored closed in the original packaging.

Important requirement 2.3 . applies to all respiratory protective devices. This requirement foresees the use of anti-fog products or lenses when necessary. This is necessary for full face masks that are intended for use in highly polluted and foggy atmospheres where it is not possible to remove the device for cleaning .

8.35. Skin and eye protection

ANNEX 2 (continued)

3.10.2. Skin and eye protection

PPE intended to prevent surface contact of the whole body or part of it with dangerous substances and infectious agents must be able to prevent the penetration or spread of such substances through the protective coating under foreseeable conditions of use.

The materials from which the PPE and other components of these types of PPE referred to in paragraph 1 of this item are made, must be so selected or designed and installed to ensure, as far as possible, impermeability that will allow prolonged use or, failing that, partial impermeability that limits the wearing period.

When, on the basis of their nature and foreseeable conditions of use, certain dangerous or infectious substances possess a high penetrating power which limits the duration of protection provided by PPE referred to in paragraph 1 of this item, that equipment must be subjected to standard tests. .

The PPE referred to in paragraph 3 of this item, which is considered to comply with the test specifications, must have a sign indicating the names, or, if this is not possible, the codes of the substances used in the tests and the corresponding standard protection period. The manufacturer's instructions must also contain an explanation of the codes (if necessary), a detailed description of the standard tests and all the necessary information to determine the maximum permissible wearing period in the various foreseeable conditions of use.

The protective part of this PPE will prevent direct contact of the skin or eyes with substances and mixtures that are dangerous to health and with harmful biological agents .

Personal protective equipment for protection against substances and mixtures that are dangerous to health and from harmful biological agents must be able to prevent the penetration and spread of such substances. This will be the case at least during the time of use specified in the instructions for use. In practice, all materials are limited in time, so appropriate information and warnings in the instructions for use are required.

It is not possible to test the effectiveness of protection against all substances and mixtures in all conditions. Tests with representative substances will indicate to the user the effectiveness of protection. The test substance must be clearly stated in the instructions for use so that the end user can select the appropriate PPE for their tasks. The significance of these results, e.g. breakthrough time, should be explained so that the user can understand them. Based on this, the user can assess the protection and duration of protection in their own work situation.

8.36. Diving equipment

ANNEX 2 (continued)
3.11. Diving equipment

Respiratory equipment must be able to supply the user with a gaseous breathing mixture under foreseeable conditions of use, in particular taking into account the maximum depth of the dive. Where foreseeable conditions of use so require, diving equipment must include:
1) a suit that protects the user from the pressure caused by the depth of the dive (in accordance with item 3.2 of this Annex) and / or from the cold (in accordance with item 3.7 of this Annex);
2) an alarm device designed to instantly warn the user of the imminent interruption of the supply of gaseous breathing mixture (in accordance with item 2.8 of this Annex);
3) a rescue device that allows the user to return to the surface (in accordance with item 3.4.1 of this Annex).

The term "diving equipment" is limited to equipment used for diving in an underwater (ie in a water) medium.

The respiratory tract is exposed to pressure. Breathing apparatus must be equipped with the system for automatic regulation of the system for gaseous mixtures for breathing.

In the underwater medium, the user is always exposed to pressure. Only one type of diving suit protects the user from pressure, and that is the atmospheric diving suit (ADS), which is a small articulated underwater suit for one person, anthropomorphic in shape reminiscent of armor, with complex joints under pressure that allow articulation. Flexible combinations used in practice cannot provide protection against pressure in terms of requirement 3.2. This

requirement, in terms of pressure, only imposes that the combinations must not cause new risks arising from the equipment itself. The warning device shall form an integral part of the breathing apparatus as required in Article 3.11, paragraph 1 .

A rescue suit that allows quick evacuation of the diver must not be mixed with the diving suit. This rescue equipment (which is called a " floating compensator"), which provides to the diver the means to control buoyancy and the posture in which the head is above water, even if the user has lost consciousness and in emergencies to return to the surface, is worn independently, over a diving suit.

9 ANNEX 3 - Technical documentation for PPE

ANNEX 3

TECHNICAL DOCUMENTATION FOR PPE

The documentation referred to in Article 8 of this Rulebook must contain all relevant information on the means used by the manufacturer to ensure that the manufactured PPE complies with the essential health and safety requirements relating to that equipment.

In addition to the data referred to in paragraph 1 of this Annex, the technical documentation must contain, in particular:

1) a complete description of the PPE and its intended purpose;

2) assessment of the risks from which the PPE should protect;

3) a list of essential health and safety requirements applicable to PPE;

4) design and production drawings and schemes of PPE and its components, subassemblies and circuits;

5) descriptions and explanations necessary for understanding the drawings and schemes referred to in item 4) of this Annex as well as for the manner of work of PPE;

6) list of applied Serbian standards referred to in Article 14 of this Rulebook or in case of their partial application, indication of their parts during the design and construction of PPE;

7) descriptions of the applied technical specifications in order to meet the essential requirements for health and safety in the case when the Serbian standards or their parts have not been applied;

8) results of calculations, checks and inspections carried out in order to check the compliance of PPE with the applicable essential health and safety requirements;

9) test reports conducted to verify the compliance of PPE with the applicable essential health and safety requirements and, if necessary, to determine the appropriate class of protection;

10) description of the means used by the manufacturer in the production of PPE in order to ensure compliance of the produced PPE with the project specifications;

11) a copy of the instructions for use and information from item 1.4. Annex 2 to this Rulebook;

12) all necessary instructions for the production of PPE on the basis of the approved basic model, in the case of individually produced PPE, tailored to a specific user;

13) for PPE produced in batches in which each product is adapted to a particular user, a description of the measures taken by the manufacturer during adaptation and production to ensure that each PPE product complies with the approved type and applicable essential health and safety requirements.

The producer is obliged to harmonise the PPE they produce with the appropriate essential requirements for health and safety. The PPE producer or their representative in Serbia has the obligation to prepare technical documentation regardless of the category of PPE in question.

The technical documentation must enable an assessment to be made of the conformity of the PPE with the requirements of the Rulebook and must contain all relevant information on the means used by the producer to ensure compliance of the PPE with the essential health and safety requirements for that PPE.

In the case of PPE category II and PPE category III, in addition to the above, the technical documentation must contain:

1. producer's technical file containing:

(a) detailed PPE design documentation with, where appropriate, the prototype calculations and test results required for the MA;

(b) an exhaustive list of the essential health and safety requirements of this Rulebook and a list of the applicable Serbian standards or a list of other technical specifications applicable to the design;

2. a description of the inspection and testing devices by which the producer checks the conformity of production with Serbian standards or other technical specifications, and which ensures quality maintenance;

3. a copy of the written information with the data from item 1. 4 of Annex 2 (such as instructions on use, maintenance, storage, PPE performance, level of protection, etc.)

The producer or their representative must keep the technical documentation and make it available on request to the competent inspector for at least ten years after the date of manufacture of PPE or ten years after the date of the last manufactured specimen in the case of series production of PPE.

In any case, it is necessary for the PPE producer to assess the level of risk from which the user for whom the PPE is intended will be protected. This risk assessment is essential for the correct categorisation of PPE, and in connection with that for the adequate application of the provisions of the Rulebook.

If the producer does not have the necessary testing capacity or expertise they can of course seek the help of a third party. However, even if a third party participates in the risk assessment and conformity assessment process, the producer assumes full responsibility for the PPE's compliance.

In connection with the classification of PPE in a particular category, one should be governed by a rule that when the risk is greater than the one specified, it must be considered that the PPE belongs to a higher category.

For example: protection from sunlight is considered protection from solar radiation. This is related to eye protection and filters without corrective effect, which are designed and manufactured exclusively for the purpose of protection from indirect sunlight (sunglasses, which belong to Category I PPE).

However, if their purpose is to provide additional protection, such as, for example, from mechanical risks, splashes of molten metal, dust particles, it is correct to put them in a higher category. PPE for direct sun observation (eg solar eclipses) or for protection against radiation

from artificial light sources, such as those used in solariums, is also considered to belong to a higher category.

10 ANNEX 4-8: Conformity assessment conducted by the notified body for conformity assessment

Conformity assessment procedures are set out in the annexes:

ANNEX 4 - Internal production control (Module A)

ANNEX 5 – Assessment of type (module B)

ANNEX 6 - In accordance with the type based on internal production control (Module C)

ANNEX 7 - In accordance with the type based on internal production control and supervised testing of the product at random intervals (Module C2)

ANNEX 8 - In accordance with the type based on the guarantee of the quality of the production process - quality assurance of production (Module D)

For certain categories of PPE intended for use in conditions with a higher degree of risk (categories PPE II and III), the producer is obliged to ensure the implementation of the type examination procedure by the notified body for conformity assessment.

For the category of PPE is intended to be introduced in terms of the greatest risk (category III), the producer is required to, in addition to the process of the examination of the pattern of their choice ensure the implementation of one of the following two procedures: ensuring compliance with the type based on the internal control registration and supervised tests the PPE at random intervals by the notified body, or ensuring conformity to type based on a guarantee of the quality of the production process - ensuring the quality of production by the notified body.

It should be noted that a PPE producer may submit a type-examination request to only one designated conformity assessment body.

In this regard, it is necessary to submit a statement that the request has been submitted to only one conformity assessment body. The Rulebook prescribes that the conformity assessment body conducts or participates in one of the conformity assessment procedures from the Rulebook, if it meets the prescribed requirements for appointment.

If the Rulebook prescribes that a designated body participates in certain conformity assessment procedures of PPE, these procedures shall be performed exclusively by a designated body entered in the Register of Designated Bodies for the implementation of the appropriate conformity assessment procedure.

The register with data on designated bodies and the scope of designations for each individual body is available on the website of the Ministry in charge of economic affairs: https://tehnis.privreda.gov.rs

The choice of the designated body for conformity assessment is up to the PPE producer.

In practice, the question arises as to how to apply the Rulebook to variants (including those adapted to the person wearing them) of a "model " PPE.

In essence, in such cases, the following should be considered: PPE is considered a variant of a “model” PPE only if it differs from it in items that do not affect the expected protective performance of the equipment.

The producer must make a careful assessment in cooperation with the notified body.

The designated body is, in accordance with their powers, in any case responsible for assessing whether the PPE is a variant or not.

In each case and for each identified variant, the applicant shall provide the notified body for conformity assessment with a detailed description of the differences compared to the reference model and the number of sample variants required to carry out the appropriate checks and tests.

The notified body has the discretion to decide whether to allow the extension of existing type-examination certificates, or to issue new type-examination certificates for variants to be certified.

11. ANNEX 9 - Declaration of Conformity

The Declaration of conformity must be prepared and issued by the producer or their representative established in Serbia before the PPE is placed on the market or put into use.

The Declaration of conformity must confirm that the PPE has complied with all the requirements of the Rulebook. The producer or their representative established in Serbia is solely responsible for issuing the Declaration of conformity. Its essential goal is to enable the supervisory authorities to make sure that the PPE placed on the market complies with the essential health and safety requirements of the Rulebook.

ANNEX 9

DECLARATION OF CONFORMITY

The Declaration of Conformity PPE contains:

1) description of PPE, including general name, type, serial number, lot code, etc .;

2) business name, ie name and address of the manufacturer's registered office and, where applicable, his representative;

3) a statement that the Declaration of Conformity is issued under the sole responsibility of the manufacturer;

4) subject of the Declaration of Conformity (identification of PPE that enables traceability, a sufficiently clear color image may also be part of the declaration):

5) a statement that the PPE described in item 4 of this Annex is in accordance with this Rulebook.

6) reference to applied Serbian / harmonised standards; where appropriate, reference to other standards and technical specifications when applied;

7) where applicable, the business name, ie name, registered office address and unique number of the Designated Body that performed the Type Examination, the number of the Type Examination Certificate, as well as the reference to that Certificate.

8) where appropriate, the conformity assessment procedure applied in accordance with Annex 7 or Annex 8 to this Rulebook, under the supervision of the Designated Body whose name and unique number are given.

9) additional information: place and date of issuance of the Declaration;

10) identification and signature of the authorised person, responsible for drawing up the Declaration of Conformity on behalf of the manufacturer or his representative.

Each copy of the PPE does not have to be accompanied by a Declaration of conformity, but the supplier must ensure its availability upon request to the competent authorities.

For PPE of all categories, the Declaration of conformity must confirm that the PPE meets the essential health and safety requirements of the Rulebook, and the text of the Declaration must comply with the requirements of the Rulebook.

It is important to note that for PPE categories II and III, the Declaration of conformity must additionally show that the PPE conforms to the type / model for which the type examination certificate has been issued.

The name, address and unique number of the notified body that issued the type-examination certificate (unique number from the Register of Designated Bodies) must be entered on the Declaration of conformity, as well as the number of the type-examination certificate.

For category III PPE, the following additional elements must be entered in the declaration:

Business name, i.e. name, registered office address and unique number of the notified body that performed the sample testing in the process of ensuring compliance with the type of PPE based on internal production control and supervised testing of PPE at random intervals (unique number from the Register of notified bodies) and test report number , ie, when appropriate, business name, ie name, seat address and unique number of the designated body that approved the quality system of the PPE production process (unique number from the Register of Designated Bodies) and the number of the document by which that approval was made.

The PPE supplier shall keep the original copy of the Declaration of Conformity or its photocopy with translation into Serbian, if the PPE is not manufactured in Serbia, and it must be available and available to the competent inspector, at least ten years after the date the PPE was produced or from the date the last copy of the PPE was made in the case of serial production.

The model of the Declaration of Conformity of PPE is given below.

MODEL OF THE DECLARATION OF PPE CONFORMITY

DECLARATION OF CONFORMITY

Manufacturer (or his representative in the Republic of Serbia)

....

(business name and address of the registered office of the manufacturer or his representative in the Republic of Serbia, and if the PPE is imported, also state the business name and address of the registered office of the legal entity, ie the name of the natural person / entrepreneur who has its registered office / residence in the Republic of Serbia is responsible for ensuring the availability of technical documentation)

Declares that PPE is described here ..... (description of PPE - production, type, serial number)

and intended for .... (purpose of PPE),

harmonised with the requirements of the Rulebook on personal protective equipment ("Official Gazette of RS", No. 23/20), as well as the requirements .... (specify other regulations with which the PPE is harmonised, if applicable),

and harmonised with the following Serbian standards by which the appropriate harmonised standards have been adopted .... (specify other standards, ie technical specifications that have been applied, if applicable)

 That it is identical to the PPE for which the Type Certificate no. ..... in accordance with Article 18 and Annex 5 of the Ordinance by ..... . (Indicate the name, address and unique number of the notified body that issued it, from the Register of Designated Bodies),

** That the procedure referred to in Article 18 and Annexes 7 and 8 of the Ordinance has been carried out for PPE by .... (state the name, address and unique number of the designated body that issued it, from the Register of Designated Bodies, as well as the number of the document issued by that body)

....

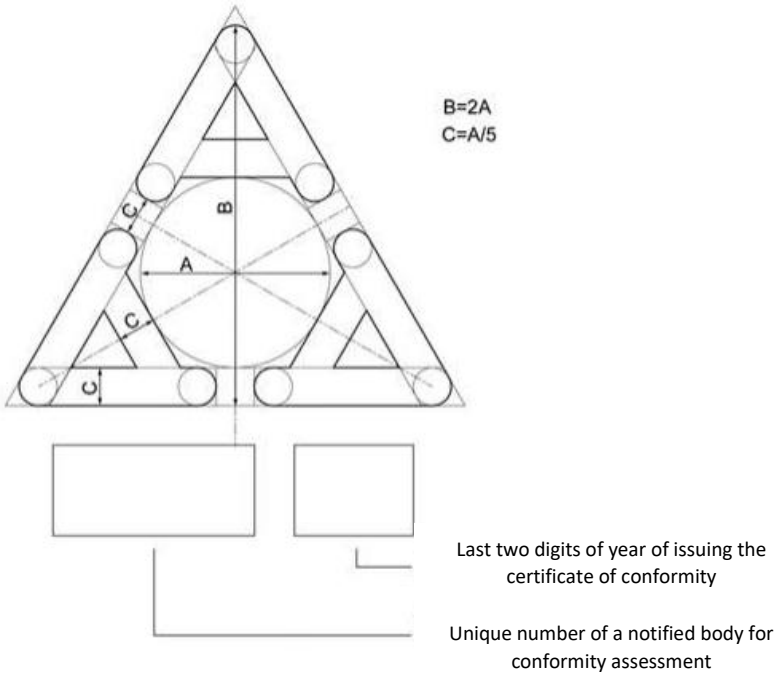
(place and date of issuance of the declaration) (identification and signature of the authorized person of the manufacturer or his representative in the Republic of Serbia)

 for PPE categories II and III

** for PPE category III

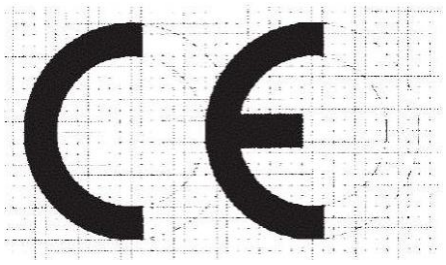
12. ANNEX 10. - Mark of conformity

The Serbian mark of conformity consists of three capital letters A connected in the form of an equilateral triangle (3A), with the appearance and content as in the picture



The size of the mark is determined according to the height of the B sign, which can only have rounded values of standard numbers according to the order of sizes R10 expressed in millimeters (mm) according to the Serbian standard SRPS A.A0.001 - Standard numbers - Rows of standard numbers. The height of the B sign is, as a rule, at least 5mm. The Serbian mark of conformity shall be accompanied by a unique number of the Designated Conformity Assessment Body from the register of designated conformity assessment bodies, as well as the last two digits of the year of issuance of the conformity certificate, if that body conducted or participated in conformity assessment.

The CE mark of conformity consists of the stylized Latin letter mark "CE" in the following form:



The various components of the CE marking must have substantially the same height, which may not be less than 5 mm. If the CE mark is reduced or enlarged, the proportions shown in the drawing in paragraph 1 of this Annex must be obeyed.

From the day of application of this Rulebook until the day of entry into force of the ACAA agreement for PPE to which this Rulebook applies or, if that agreement is not concluded, until

the day of accession of the Republic of Serbia to the European Union, marking of PPE conformity is performed by application of Serbian conformity mark in accordance with this rulebook and special regulations.

13. APPENDIX: Instructions for categorisation of personal protective equipment (PPE)

FIRST PART: PPE BY TYPE

Type of PPE		Category certification	Reason
1.	**Hearing protection equipment**		
1.1.	All hearing protection equipment (whether worn on the head or placed in the ears)	III	3.3 . (m)
Except :			
1.2.	Plugs intended for swimmers to prevent water from penetrating the ears	It's not a PPE	Definition of PPE
1.3.	Earplugs , which are not designed to protect from danger, for example. suppositories for sleeping and suppositories for use during flight	It's not a PPE	Definition of PPE

Type of PPE		Certification category	Justification
2.	Eye protection equipment		
2.1.	All eye protectors and filters , including eye protectors against artificial UV radiation (eg. in the solarium) and goggles for phototherapy for babies	II	3.2.
Except:			
2.2.	Eye protectors and filters designed and manufactured for use in the high temperature effects of which are comparable with the effect of an air temperature of 100 ° C or more, and which may or may not be characterised by the presence of infrared radiation, flame, hot spraying or projection of large amounts of molten materials	III	3. 3. (e)
2.3.	Eye protectors and filters designed and constructed to protect against ionizing radiation	III	3. 3. (d)

2.4.	Eye protectors and filters designed and constructed for protection against electric shock	III	3.3. (h)
2.5.	Goggles and masks for swimming and / or diving	I	3.1. (a)
2.6.	Eye protectors and filters designed and manufactured exclusively for protection from sunlight, sunglasses (not corrective) for private and professional use. This includes instances where the glasses are tinted after manufacture or any assemblance after manufacture (e.g., with the setting of the lens for protecting against sunlight and the frame which is not CE marked)	I	3.1. (d)
2.7.	Ski goggles of all kinds except corrective goggles	I	3.1. (d)
2.8.	Corrective goggles including corrective sunglasses Note: If corrective goggles provide protection beyond protection from sunlight (eg from shock, wear, etc.), they are classified as personal protective equipment of the category corresponding to the risk from which they protect.	It depends on the risk they protect against	See http://ec.europa.eu/DocsRoom/documents/10262/attachments/1/translations/en/renditions/pdf
2.9.	Visors mounted in helmets designed and constructed for use on motor vehicles with two or three wheels	It's not a PPE	2.5.
Type of PPE		Certification category	Justification
3.	Equipment for protection against falls from heights		
3.1.	All protective equipment designed and manufactured for protection against falls from heights, for individual or professional use (work at heights, falls from ships, hiking, rock climbing , speleology, etc.). This category also includes height and support equipment (belts , thigh straps, belts, etc.) and lowering equipment with built-in speed control system Note: This equipment includes belts (thigh straps, shoulder straps, etc.) and all accessories intended to attach a person to the structure, except for anchor points that are an integral part of the structure or rock. E.g: • for professional use: connecting ropes , movable fall stop , carabiners, couplings , connectors, anchor points, etc.	III	3.3. (g)

	• for hiking, mountain climbing and speleology: dynamic ropes for climbing , keyways , clamps (karabiner for climbing), terminals for rope , pins , anchors for the walls (pythons) , anchors for ice , the tools for ice that may serve as the anchoring point (e.g. for climbing) etc. Note: The categorisation is not affected by the fact that the equipment is factory-made / assembled or manufactured / assembled by the user (employer) (eg double ropes)		
Except:			
3.2.	Points of support that are an integral part of the structure or walls or requiring tools for its setting Example: Anchor devices of class A, C and D according to EN 795: 201214 [1]	It's not a PPE	Definition of PPE The reader's attention is drawn to the warning published in the OJEU regarding E N 795: 2012 , see: https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/personal-protective-equipment_en
3.3.	Equipment for accessing or leaving a position at height (winch seats , lowering equipment without built-in speed controllers , etc.)	It's not a PPE	Definition of PPE
3.4.	Climbing equipment, mountaineering , speleology, etc. (hammers, equipment to lower without built-in speed regulator , climbing equipment using ropes etc.).	It's not a PPE	Definition of PPE
3.5.	Equipment with support (belts, etc.) designed and made for use with parachutes, paragliders, kites, etc. and which cannot be used for purposes other than those for which they are designed	It's not a PPE	Definition of PPE
3.6.	Parachutes for emergencies	It's not a PPE	2.4.

Type of PPE		Certification category	Justification
4.	Head protection equipment Note: Equipment that protects against several risks of different categories is subject to a stricter conformity assessment procedure		
4.1.	Helmets , including protection of the head from mechanical shocks in sports .	I I	3.2.
Except:			
4.2.	Helmets designed and made to provide protection, including thermal protection, for use in an environment of high temperature, and the effects comparable to the effects of air temperature of 100 ° C or more, and which may or may not be characterised by the presence of infrared radiation, flame, hot spraying or projecting large amounts of molten material .	I II	3.3. (e)
4.3.	Helmets for protection of the head projected and made to provide protection, including thermal protection for use in low temperature environments, whose effects are comparable with air temperature of -50 ° C or lower .	I II	3.3. (f)
4.4.	Head protection equipment designed and constructed for protection against electric shock .	I II	3.3. (h)
4.5.	Lightweight head equipment designed and manufactured to protect the scalp from minor shocks effects of which cannot cause permanent injury .	I	3.1. (a)
4.6.	Helmets designed and constructed for drivers of motor vehicles on two or three wheels , including racing helmets Note: Helmets for the racing cars are not excluded from the Regulation on PPE but belong to PPE category II	It's not a PPE	2.5 .
4.7.	Helmets designed and constructed specially for the armed forces or for use in the maintenance of public order and peace .	It's not a PPE	2.1.
Type of PPE		Certification category	Justification
5.	Equipment for complete or partial protection of persons		
5.1.	All equipment	II	3.2.
Except:			
5.2.	Equipment designed and manufactured for use in high temperature environments effects of which are comparable to air temperatures of 100 ° C or higher and which may or may not be characterised by the presence of infrared radiation, flames, hot sprays or the projection of a large amount of molten material .	III	3.3. (e)

5.3.	Equipment designed and manufactured for use in low temperature environments whose effects are comparable to air temperatures of –50 ° C or lower .	III	3.3. (f)
5.4.	Equipment designed and manufactured for protection against electric shock .	III	3.3. (h)
5.5.	Visors designed and manufactured for incorporation into helmets used by drivers of motor vehicles with two or three -wheels, including racing visors.	It's not a PPE	2.5.
Type of PPE		Certification category	Justification
6.	Protective clothing		
6.1.	All items of clothing with accessories (detachable or not), designed and made to provide special protection Note: This category also includes: • protective clothing used for sports activities, such as diving and immerison suits that provide thermal protection, protective clothing for water skiing, etc .; • protective clothing, such as coveralls and two-piece suits, which provide thermal protection in case of accidental fall into the water ; • clothing that provides additional protection against tick bites ; • equipment for beekeepers , especially beekeper hats and clothing to protect against bee stings, with the exception of clothing, which only protects against dirt, and from the smokers.	II	3.2.
Except:			
6.2.	Clothing with accessories (detachable or not) designed and made for protection against electric shock.	III	3.3. (h)
6.3.	Clothing with accessories (detachable or not) designed and made for use in high temperature environments effects of which are comparable to air temperatures of 100 ° C or higher and which may or may not be characterised by the presence of infrared radiation, flames, hot sprays or projections of large amounts of molten material Example: protective clothing for firefighters .	III	3.3. (e)
6.4.	Clothing with accessories (detachable or not) , designed and made for use in low temperature environments effects of which are comparable to air temperatures of -50 ° C or lower .	III	3.3. (f)

6.5.	Clothing with accessories (detachable or not) , designed and made so as to provide only limited protection of the substance or mixture that are dangerous to health, harmful biological agents or ionizing radiation Note: The producer must specify the products from which protection is provided and the duration of such protection .	III	3.3 . (a) and (c) - (d)
6.6.	Clothing with accessories (detachable or not) , designed and manufactured so as to provide complete isolation of the respiratory tract from the atmosphere, including the one for diving .	III	3.3. (a) - (d)
6.7.	Clothing with accessories (detachable or not) , designed and manufactured for protection against liquid chemicals Note: The producer must indicate the products against which protection is provided and the duration of such protection	III	3.3. (a)
6.8.	Protective equipment resistant to bullets and stab wounds, which is not used by the armed forces, but, for example , by security officers .	III	3.3. (i)
6.9.	Clothing with accessories (detachable or not) for professional use designed and manufactured for protection from atmospheric conditions which are neither exceptional nor extreme, such as rain and splash water .	I	3.1. (e)
6.10.	Clothing with accessories (detachable or not) , designed and manufactured so to provide protection against mechanical actions effects of which are superficial.	I	3.1. (a)
6.11.	Clothing with accessories (detachable or not) , designed and made thus to provide protection against the risks arising from the application of hot components which do not expose the user to a temperature of over 50 ° C or dangerous impacts .	I	3.1. (c)
6.12.	Clothing with accessories (detachable or not) , designed and made in particular for use in the armed forces or to maintain the order and peace, including bullet-resistant clothing or jackets, clothing protecting from biological contamination or ionizing radiation Note: The examples of protective clothing that is not used by the armed forces or are not used for the maintenance of public order and peace are PPE and should be categorised according to the type of risk from they protect against.	It's not a PPE	2.1.
6.13.	Clothing with accessories (detachable or not) , designed and made for the protection from adverse atmospheric conditions	It's not a PPE	2.3.

6.14.	Ordinary clothing with accessories (detachable or not), or sports wear and / or accessories (which does not offer special protection), including uniforms	It's not a PPE	2.3.
6.15.	Clothing for bikers and extra protection See point 14		
Type of PPE		Certification category	Justification
7 .	Respiratory protection		
7 .1.	All respiratory protective equipment (irrespective of the description) designed and constructed for protection against solid aerosols, liquid aerosols or gases; All respiratory protective equipment designed and constructed to provide complete insulation from the atmosphere; all respiratory protective equipment designed and constructed for diving;	III	3.3 . (a) - (d)
Except:			
7 .2.	All respiratory protective equipment designed and constructed specifically for use in the armed forces or for the maintenance of public order and peace	It's not a PPE	2.1.
7 .3.	Surgical masks Note: If such masks are also intended to protect users from microbiological and virus infections, etc., then they are also PPE category III (personal protection and medical use)	It's not a PPE	See interpretative document between PPED and MDD[2] http://ec.europa.eu/DocsRoom/documents/10262/attachments/1/translations/en/renditions/pdf
7 .4.	Nose plugs intended for swimmers to prevent water from penetrating the nose	It's not a PPE	Definition of PPE
7 .5.	Nasal filters that mostly prevent the inhalation of pollen and other allergens	It's not a PPE	Definition of PPE
Type of PPE		Certification category	Justification
8 .	Foot and/or foot protection and anti-slip equipment		
8. 1.	All the equipment with features (detachable or not) designed and manufactured in particular for the protection of the foot and /or leg against slipping, for example. snow and ice spikes; Note: This category also includes protection against static electricity because this equipment is used in potentially explosive environments;	II	3. 2.

Except:			
8 .2.	Equipment with accessories (detachable or not) designed and manufactured for the protection against electric shock in the course of work involving hazardous voltages or used to provide insulation against high voltage	III	3.3 . (h)
8.3 .	Equipment with accessories (detachable or not) designed and manufactured for use in the environments of high temperature, and the effects comparable to air temperatures of 100 ° C or more, and which may or may not be characterised by the presence of infrared radiation, flame, flame or projections of large amounts of molten material	III	3.3. (e)
8.4.	Equipment with accessories (detachable or not), designed and constructed for use in low temperature environments, effects of which are comparable with air temperature of - 50 ° C or lower.	I II	3.3. (f)
8.5.	Equipment with accessories (detachable or not), designed and constructed so as to provide only limited protection from the substance or mixture dangerous for health, harmful biological agents or ionizing radiation ; Note: The producer must indicate from which products and equipment it protects against and how long this protection lasts	III	3.3. (a), (c) and (d)
8.6.	Sporting equipment (especially sports shoes) with accessories (detachable or not), designed and manufactured to protect against superficial mechanical injuries Note : Sports shin guards (eg for football, hockey) and protective equipment generally belong to PPE category II, unless designed only for protection against superficial mechanical injuries.	I	3.1. (a)
8.7.	Equipment with accessories (detachable or not), for professional use , designed and constructed to protect against weather conditions which are neither exceptional nor extreme	I	3.1. (e)
8.8.	Equipment with accessories (detachable or not) for personal use , designed and constructed to protect against atmospheric conditions	It's not a PPE	2.3.
8.9.	Equipment with accessories (detachable or not) , designed and constructed in particular for use in the armed forces, or in the maintenance of public order and peace, including protection from the biological contamination or ionizing radiation	It's not a PPE	2.1.
8.10.	Some footwear , especially sports shoes, which contain components intended to absorb pressure when walking, running,	It's not a PPE	Definition of PPE

	etc. or components that provide good contact with the substrate or stability . These components should be considered as provided for increasing comfort Note: This category includes especially football shoes and sneakers with crampons ;		
Type of PPE		Certification category	Justification
9.	Hand and arm protection equipment		
9.1.	All equipment with accessories (detachable or not) designed and manufactured especially as a protection for the hands and/or arms; Note: this includes all equipment or clothing that protects the hand or part of the hand, including gloves, fingerless gloves , clothing that protects only the fingers or only the palm, etc.	I I	3.2.
Except:			
9.2.	Equipment with the features (detachable or not) designed and made for the protection of the hazards associated with electricity during work involving hazardous voltages or used to provide insulation against high voltage	III	3.3. (h)
9.3.	Equipment with the accessories (detachable or not), including the fire-fighting equipment, designed and and made for use in environments of high temperature, and the effects comparable to air temperatures of 100 ° C or more, and which may or may not be characterised by the presence of the infrared radiation, flames, hot splashes or projections of large amounts of molten material , including equipment for firefighters , gloves for welding, etc	III	3.3. (e)
9.4.	Equipment with accessories (detachable or not) , designed and made and for use in low temperature environments, effects of which are comparable with air temperature of -50 ° C or lower .	III	3.3. (f)
9.5.	Equipment with accessories (detachable or not) , designed and constructed to provide only limited protection of the substance or mixture that are dangerous to health, harmful biological agents or ionizing radiation; Note: The producer must indicate the products against which protection is provided and the duration of such protection	III	3.3. (a), (c) and (d)
9 .6.	Equipment with accessories (detachable or not) for professional use designed and manufactured as a protection against means for cleaning with a mild effect (for washing dishes, cleaning etc.).	I	3.1. (b)

9.7.	Equipment with accessories (detachable or not) designed and manufactured for protection against mechanical actions influence of which is superficial (pricks due to sewing, gardening, dirty work, sports - including gloves for boxing bag - etc.) ;	I	3.1. (a)
9.8.	Equipment with accessories (detachable or not) for personal use , designed and constructed for protection from the heat and the risks that occur in the application of hot components, and which does not expose the user to a temperature greater than 50 ° C or dangerous impacts and for professional use for protection from incredibly cold weather	I	3.1. (c) and (d)
9.9.	Gloves and finger guards for medical use in the patient's environment	Depending on the type of protection	See the interpretative document between PPED and MDD[3] http://ec.europa.eu/DocsRoom/documents/10262/attachments/1/translations/en/renditions/pdf
9.10.	Gloves designed and made for personal use for protection against adverse weather conditions, moisture and water or cold;	It's not a PPE	2.3.
9.11.	Equipment with accessories (detachable or not) , designed and produced in particular for use in the armed forces, or in the maintenance of public order, including protection from the biological contamination or ionizing radiation ;	It's not a PPE	2.1.
9.12.	Boxing gloves Note: Boxing bag gloves are PPE category I	It's not a PPE	Definition of PPE
9.13.	Dry gloves for divers	II	3.2.
9.14.	Gloves for protection against harmful biological agents (e.g. microorganisms)	III	3.3. (c)
9.15.	Gloves for personal use for heat protection	II	3.2.

PART TWO: by type of risk

Note: the tables in this part contain all types of PPE and are not in conflict with the tables in part 1. They are given only for further clarification.

Type of PPE		Certification category	Justification
10.	Equipment for protection against drowning and or maintenance of water		
10.1.	All the equipment designed and constructed to prevent drowning and which is used as an auxiliary and which includes a buoyancy aids, and swimming respectively (only intended for use in shallow water) Note: • Includes crampons and other equipment that is used to exit out of the water after a pro falling tion through the ice • Covers also swimming suits with built-in bobbers • Also includes swimming „bracelets“	II	3.2.
Except:			
10.2.	Lifebelts and vests for life saving and prevention of drowning	III	3.3. (i)
10.3.	Life belts and life jackets for the emergency needs of passengers on ships and aircraft Note: The terms "ship" and "aircraft" refer exclusively to the assets which transport passengers also on seagoing vessels to which international conventions of the International Maritime Organisation (IMO) apply. This category does not include boats for recreation (motor boats and sailing boats), fishing boats, work boats, etc .	It's not a PPE	2.4.
10.4.	Buoyancy auxiliaries that user does not wear but holds (such as styrofoam timber, etc.).	It's not a PPE	Definition of PPE
10.5.	Buoyancy auxiliaries that are not designed to be held in place while wearing or to provide a vertical position of the user (such as rings , flotation belts , etc.).	It's not a PPE	Definition of PPE
10.6.	Ropes to exit the water after falling through the ice	It's not a PPE	Definition of PPE

11.	Equipment that protects against electrical hazards	Certification category	Justification
11.1.	Electric shock protection equipment Note: Dangerous voltage means a voltage equal to or greater than 50 V AC or 75 V DC (D C)	III	3.3. (h)
Except:			
11.2.	Hand insulation tools	It's not a PPE	Definition of PPE
11.3.	Protective equipment (such as shoes, clothes, etc.) for protection against static electricity Note: This equipment is used in environments with a potential risk of explosion due to sparking	II	3.2.
Type of PPE		Certification category	Justification
12.	Equipment designed and constructed to protect against the effects of mechanical action		
12.1.	All PPE designed and built to protect the user from vibration	I I	3.2.
12.2.	PPE designed and constructed to protect the user's skin from friction (eg reinforcements)	I	3.1. (a)
12.3.	PPE designed and manufactured to protect users from the increased level of a risk that arises from collisions with other persons or falls during sports (eg. back protectors for bikers, shin protectors for football players, protectors for ice hockey ...)	I I	3.2.
12.4.	PPE designed and constructed to protect the user from shock occurring as a result of gravitational force (eg. collar for cart drivers, collar neck for car races drivers. ..)	I I	3.2.
12.5.	PPE designed and constructed to protect users from high pressure nozzles with an operating pressure of more than 200 bar	I II	3.3. (k)
Except:			
12.6.	Equipment for protection against superficial mechanical injuries (such as helmets, gloves , footwear , etc.)	I	3.1. (a)
12.7.	Sports equipment for protection against minor shocks due to falls (protection against bruises, lacerations, minor burns ...), such as volleyball knee pads	I	3.1. (a)
12.8.	Equipment designed and manufactured to enhance comfort and performance , such as footwear and gloves, for example. running shoes and sports gloves that contain components designed to absorb pressure when walking, running, etc. or provides good adhesion or stability	It's not a PPE	Definition of PPE

12.9.	Needle protectors	It's not a PPE	Definition of PPE
Type of PPE		Certification category	Justification
13.	Rescue equipment		
13.1.	Masks for resuscitation: if the mask , in addition to facilitating proper artificial respiration, has also a protective function for the rescuer (e.g. control of infection in contact in the mouth of the victim - in this case it is PPE)	In the dependin g ity of speci es protection	3.2.
13.2.	If the rescue equipment is worn before the accident that requires rescue, then it is PPE Example: A wet suit that is worn continuously to prevent hypothermia in case of falling into the water is PPE	Depending on the type of protection	3.1. (a)
13.3.	Equipment used by the rescuer for their own protection Example: respiratory tract protection equipment used by firefighters when dragging people from smoky buildings	Depending on the type of protection	3.2.
13.4.	Airbags for protection from avalanches	I I	3.2.
Except:			
13.5.	If rescue equipment is placed on a person after an accident, then that equipment is not PPE Example: sling used to rescue an unconscious person to inaccessible places	It's not a PPE	Definition of PPE
Type of PPE		Certification category	Justification
14.	Equipment for motorcyclists		
14.1.	Helmets for motorcyclists	It's not a PPE	2.5.
14.2.	Bikers garments and additional protection such as gloves for personal use as long as providing protection from climatic conditions only	It's not a PPE	2.3.
Except:			
14.3.	Bikers garments and additional protection for professional use (eg. gloves, boots) only for the protection of the climate	I	3.1. (e)
14.4.	Bikers garments and additional protection (eg, gloves, shoes) that offers additional protection (eg. air pillow protectors of shock and limbs or back, pads for elbow or shoulders, protection against cuts and abrasions ...)	I I	3.2.
Type of PPE		Certification category	Justification
15.	Clothes noticeable from a great distance		
15.1	Clothes noticeable from a great distance	II	
15.2	Accessories visible from a great distance (eg. reflecting labels, hanging accessories such as the suspension labels)	II	3.2.

15.3.	Hunting jacket made of fluorescent material to signalise the presence of the user	II	3.2.
Except:			
15.4.	Devices of high visibility (ie. Reflecting keychains, backpacks with reflective and/or fluorescent material, etc.).	It's not a PPE	Definition of PPE
Type of PPE		Certification category	Justification
16.	UV protection		
16.1.	Eye protection from natural UV radiation (normal level) Example: sunglasses	I	3.1. (d)
16.2.	Eye protection from natural UV radiation (higher level) Example: sunglasses	II	3.2.
16.3.	Eye protection from artificial UV radiation Safety goggles with specific UV protection properties (eg welding goggles)	II	3.2.
16.4.	Eye and skin protection from artificial UV radiation . Example: face shields with specific UV protection properties	II	3.2.
16.5.	Skin protection against artificial UV radiation All clothing, including clothing for the whole body or body parts , hats and helmets, gloves and footwear, designed and manufactured to have specific UV protection properties against artificial UV radiation (eg welder 's clothes)	II	3.2.
16.6.	Skin protection from natural UV radiation All clothing, including clothing for the whole body or parts of the body , hats and helmets, gloves and footwear, designed and manufactured to have specific UV protection properties	I	3.1. (e)

Legend:

1.1	1) personal protective equipment (PPE) - is equipment designed and manufactured so that it is worn or held by the user for his own protection from one or more dangers to his health and safety, as well as:	**Article 3.1 of the Rulebook**
1.2	(1) replaceable PPE components that are essential for its protective function,	**Article 3.1 (1) of the Rulebook**
1.3	(2) PPE connection systems which are not intended to be held or carried by the user, which are designed to connect that equipment to an external device or a reliable anchorage, which are not designed to be permanently attached and which do not require attachment before use;	**Article 3.1 (2) of the Rulebook**
2.	This Rulebook applies to PPE referred to in Article 3, paragraph 1, item 1) of this Rulebook.	**Article 2**
2.1	1) PPE designed and constructed specifically for the armed forces or for the maintenance of public order and peace;	**Article 2 1)**

2.2	2) PPE designed for self-defense, with the exception of PPE intended for sports activities;	**Article 2 2)**
2.3	3) PPE designed and constructed for private use and used for protection against: (1) atmospheric influences that are not of an extreme nature, (2) moisture and water when washing dishes;	**Article 2 3)**
2.4	4) PPE intended exclusively for use on seagoing vessels or aircraft, in accordance with special regulations;	**Article 2 4)**
2.5	5) PPE for the protection of the head, face or eyes of the user, covered by a special regulation relating to protective helmets and their visors intended for drivers of motorcycles and mopeds and their passengers.	**Article 2 5)**
	Annex 1. Categories of PPE by risk :	Annex 1. Categories of PPE by risk, Category I :
3.1 (a)	Category I. a) surface mechanical action;	**1)**
3.1 (b)	Category I. b) surface mechanical action;	**2)**
3.1 (c)	Category I. c) surface mechanical action;	**3)**
3.1 (d)	Category I. d) surface mechanical action;	**4)**
3.1 (e)	Category I. e) surface mechanical action;	**5)**
3.2	Category II. covers risks not listed in categories I and III	
3.3 (a)	Category III: a) substances and mixtures which are dangerous to health;	**1)**
3.3 (b)	Category III: b) oxygen-deficient atmosphere;	**2)**
3.3 (c)	Category III: c) harmful biological agents;	**3)**
3.3 (d)	Category III: d) ionizing radiation	**4)**
3.3 (e)	Category III: e) high temperature environments effect of which can be compared with the effect of air temperature of + 100 ° C or higher;	**5)**
3.3 (f)	Category III: f) low temperature environments effects can be compared with the effect of air temperature of -50 ° C or lower;	**6)**
3.3 (g)	Category III: d) falls from a height;	**7)**
3.3 (h)	Category III: h) electric shock and live operation;	**8)**
3.3 (i)	Category III: i) drowning;	**9)**
3.3 (j)	Category III: j) cuts when working with a hand-held chainsaw;	**10)**
3.3 (k)	Category III: k) high pressure jets;	**11)**
3.3 (l)	Category III: l) gunshot wounds or stab wounds;	**12)**
3.3 (m)	Category III: m) harmful noise.	**13)**