REPUBLIC OF SEBIA
Ministry of Finance and Economy

HANDBOOK FOR IMPLEMENTATION OF RULEBOOK ON PERSONAL PROTECTIVE QUIPMENT

BMZ Federal Ministry for Economic Cooperation and Development

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Handbook for implementation of Rulebook on Personal protective equipment

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Content

INSTRUCTIONS FOR IMPLEMENTATION OF RULEBOOK ON PERSONAL PROTECTIVE EQUIPMENT

1. INTRODUCTION (LEGAL BASIS, STRUCTURE AND A LINK TO EU LEGISLATION)

The legal basis for the adoption of the **Rulebook on personal protective equipment** ("Official Gazette of RS", No. 100/11 - hereinafter referred to as "**the Rulebook**") is defined in Article 6, Paragraph 1, of the Law on Technical Requirements for Products and Conformity Assessment ("Official Gazette of RS", No. 36/09 – hereinafter referred to as "**the Law**"), which stipulates that technical regulations are prepared and adopted by the competent line ministry.

The Rulebook was adopted by the Minister of Economy and Regional Development, responsible for technical requirements for industrial products.The Rulebook was published on 29th December, 2011, and it came into force on 6, January 2012, and shall apply as of 1, July 2013.

This Rulebook is in compliance with all principles and essential requirements of **Directive 89/686 EEC of the European Council of 21 December 1989. on the approximation of the laws of the Member States relating to personal protective equipment**, as well as its modifications by Directive 93/68/EEZ of 22, July 1993, Directive 93/95/EEZ of 29, October 1993, and Directive 96/58/EEZ of 3, September 1996, which is all in line with the obligations of Republic of Serbia under Stabilization and Association Agreement (SAA), and National Program for Integration of Serbia to the European Union (NPI).

In the process of preparation of the Rulebook, the relevant solutions in the field of EU technical legislation were taken into account, especially the Decision No. 768/2008 of the European Parliament and the Council on a Common Framework for the Marketing of Products.

Useful information on current EU regulations in the field of PPE, including the text of the Directive No. 89/686, can be found at the following website:

http://ec.europa.eu/enterprise/sectors/mechanical/personal-protective-equipment

The instructionsare not meant to be an official interpretation of the Rulebook, but it should serve to all interested parties in order to facilitate the implementation of the Rulebook. The interested parties are considered to be primarily manufacturers, distributors and users of PPE (the Rulebook has particular importance for employers who are required to provide their employees with PPE as part of the measures for ensuring the safety and health at work), as well as designated conformity assessment bodies (hereinafter referred to as**: designated bodies**or **CABs**).

In accordance with Directive 89/686 EEC and the Law, entirely new solutions in the field of personal protective equipment (hereinafter referred to as: **PPE)** aredefined in the Rulebook, as well as subjects carrying out conformity assessment, types of conformity certificates and classification of PPE. Furthermore, conformity of the product is achieved through the voluntary implementation of Serbian standards transposing harmonized (European) standards in this field. This concept differs significantly from the concept of old regulations for PPE, which often consisted of outdated, inconsistent and too complex technical and technological solutions and policies, imposing sometimes unnecessary restrictions and encumbrances for manufacturers and other suppliers of PPE.

Structure of the Rulebook

In the first section-introductory provisions, the scope of the Rulebook is defined, i.e. the products to which the Rulebook applies, as well as the products to which the Rulebook does not apply, and definitions of key terms.

The second section contains provisions which regulate placing on the market of PPE, essential requirements for health and safety related to PPE, and free movement of PPE.

The third section contains provisions on classification of PPE, conditions for placing on market of different categories of PPE, as well as provisions on classification of PPE in appropriate categories.

The fourth section defines conformity assessment procedures for PPE and conditions which must be fulfilled by conformity assessment bodies.

The fifth section is related to the presumption of conformity and Serbian standards transposing harmonized (European) standards.

The sixth section contains provisions on technical documentation for PPE and declaration of conformity.

Theseventh section contains provisions for marking of PPE.

The eighth section contains a safeguard clause.

The ninth section stipulates transitional and final provisions, i.e. the change of terminology upon accession of Serbia to EU and/or the signing of an ACAA agreement, provisions on termination of validity of old Serbian regulations and their application in the transitional period, and provisions on entry into force and start of implementation of the Rulebook.

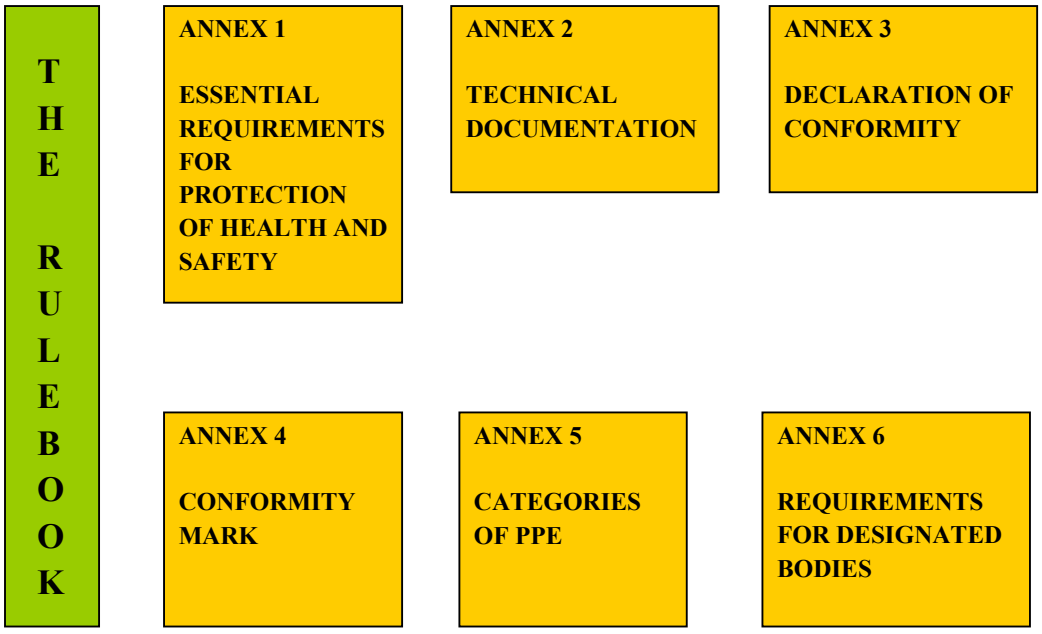
Annex 1 contains provisions on essential requirements for health and safety of PPE.

Annex 2 stipulates the content of technical documentation.

Annex 3 stipulates the content of declaration of conformity.

Annex 4 specifies the outline and the content of Serbian mark of conformity and of CE mark. Annex 5 classifies PPE into categories.

Annex 6 contains requirements that must be met by a designated conformity assessment body for PPE.



Structure of the Rulebook

2. SCOPE OF THE RULEBOOK

2.1. Products within the scope of the Rulebook.

The Rulebook applies to PPE intended for domestic, sports and leisure activities, as well as for professional use.

The Rulebook defines PPE as any equipment (device, appliance, instrument, etc.). designed to be worn or held by an individual for protection against one or more health and safety hazards, as well as:

(1) a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks (e.g. helmet coupled with a visor);

(2) a protective device or appliance combined, separately or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity (e.g. knee protectors included in trousers used for performing work whilst kneeling);

(3) interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment (e.g. filters for respiratory protective devices and screens for eye protectors).

Any system placed on the market in conjunction with PPE for its connection to another external, additional device shall be regarded as an integral part of that equipment even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure (e.g. air line linking respiratory equipment to a compressor).

PPE is "worn" in the sense that clothing, glasses, hearing protectors are worn. Indeed much PPE is clothing, be it garments, headgear, gloves or footwear. Other PPE is to be "held" in the hand, such as screens to protect the eyes and face during welding.

The protection provided by PPE thus depends on an action by the person exposed to the hazard. Portable equipment which is neither worn nor held during use is not considered as PPE. So, for example, insulating mats or stools used by electricians for live working, or protective screens placed in the work stations are not regarded as PPE.

PPE is worn or held "by an individual". This is what distinguishes personal equipment from collective protective equipment. Significantly, the terms of the definition of PPE place it within the broad field of the protection of persons. The field of PPE is not limited to equipment used by employees or workers in general, but extends to areas unconnectedwith work, such as sports and leisure activities. Sunglasses, cycling or riding helmets, gardening gloves, shin-guards for footballers, harnesses for mountaineering, are all PPE.

PPE is used "for protection" of the individual.Generally PPE forms a shield between part of the body and the hazard for the protection of the individual against any type of risk: a shield of leather against rough surfaces which may graze the skin on hands, a shield of filtering glass against radiation which may injure the eyes, a shield of lead against X-rays which can damage body cells, and so on. This role of PPE as a shield is underlined by the pictograms chosen by PPE standards to symbolize protection against different hazards: a symbol represents the hazard for a specific PPE.

On the other hand, equipment warning against risks, but which do not have a protective function, such as stand alone alarm devices e.g., gas detectors or oxygen depletion detectors, are not classed as PPE. However, if these devices are integrated in the PPE then they are to be considered as integral part of the PPE.

PPE protects against "one or more hazards". Risk is generally defined as the conjunction of two elements: a hazard, which is a phenomenon which may cause harm, and the probability of a person being exposed to that hazard. Since PPE is designed to protect against hazard, its function is to prevent the

occurrence of harm to the exposed person. Consequently, when several risks exist simultaneously, the PPE has to protect against all the risks, not just against one of them.

PPE shall be differentiated from equipment used after harm has occurred, such as rescue or first-aid equipment, which also tends to be used by third parties. Equipment used by a rescuer is not classed as PPE, unless used to protect the rescuer himself, for example, respiratory protective devices used by firemen when retrieving people from smoke-filled buildings.

The hazards involved are those which may harm the equipment user. Equipment used to protect people other than the wearer, such as masks used to protect hospital patients, are not PPE. Nevertheless all equipment worn by health care personnel to protect themselves are PPE. Similarly equipment for protecting goods, such as gloves worn to protect foodstuffs or electronic components are not PPE.

2.2. Products outside of the scope of the Rulebook

This Rulebook **shall not apply to**:

1. PPE designed and manufactured specially for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.).

2. PPE for self-defense (aerosol canisters, personal deterrent weapons, etc.).

3. PPE designed and manufactured for private use against:

(1)-adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.),
(2)-damp and water (dish-washing gloves, etc.),
(3)- heat (gloves etc.).

4. PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time.

5. Helmets and visors intended for users of two- or three-wheeled motor vehicles.

If the risks connected with the use of PPE and its properties are completely or partially covered by other specific regulations, such risks shall be governed by these specific regulations. (e.g. the following equipment, if used as permanent equipment on board is excluded from the PPE Directive: -life jackets; -immersion suits; -combinations of immersion suits with life jackets;- breathing apparatus for firemen).

Technical regulations sometimes cover a wide range of products, phenomena and/or risks.

The nature of certain products is such that it is necessary to clearly determine the purpose and intended use of the product.

Manufacturer of a PPE must properly determine the purpose of a product intended to be placed on a market.

As an example, regulations relating to toys may be taken into consideration. Equipment designed for children to protect them from one or more risks (for example. bicycle or ski helmets, ski goggles etc) are covered by the Rulebook. However, imitations of PPE (such as fire helmets imitation, imitation of protective clothing for the doctors) are covered by the regulations for toys.

If there is doubt regarding the real intended use of such toys, the products should be accompanied by a warning stating that they are toys and not PPE. If it appears that it is realistic to assume that if an imitation of PPE protects from danger, the manufacturer must be cautious.

In such cases, the manufacturer shall still be held accountable, even in the presence of a warning.

3. Categories of PPE

Given the variety and large number of products covered by the definition of PPE, the Rulebook stipulates classification of PPE into the categories.

Classification of PPE is envisaged primarily due to the different forms of risks and different risk levels, which are present when using different types of PPE.

It is stipulated that PPE is divided into the following categories: **Category I (simple), Category II (common) and Category III (complex).**

The result of this categorization is to define specific procedures for conformity assessment to be carried out before placing on the market and/or use of certain categories of PPE.

The aim of these procedures is to ensure the optimum level of health and safety for the user.

Category I includes PPE for which the manufacturer or its representative assumes the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

This category is intended to protect users against:

(1) - mechanical action whose effects are superficial (gardening gloves, thimbles, etc.),

(2) - cleaning materials of weak action and easily reversible effects (gloves affording protection against diluted detergent solutions, etc.),

(3) - risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50C or to dangerous impacts (gloves, aprons for professional use, etc.),

(4) - atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.),

(5)- minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light anti-scalping helmets, gloves, light footwear, etc.),

(6) - sunlight (sunglasses).

Category II includes PPE which is neither a Category I PPE nor Category III PPE.

For instance, all PPE designed and manufactured for prevention from drowning is considered as Category II PPE. All PPE for hearing protection is also considered to be Category II PPE.

Detailed classification of certain types of PPE in appropriate categories is given in Annex 5 of the Rulebook, including the list of PPE falling within Category II.

It is important to emphasize that the list of Category II PPE in Annex 5 is not exhaustive one. This means, in accordance with the definition of Category II PPE, that all PPE which does not belong to the definition of Category I PPE or definition of Category III PPE falls within Category II PPE, even if it is not listed in Annex 5 of the Rulebook.

Category III includes PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time.

This category shall cover exclusively:

(1) - filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;

(2) - respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;

(3) - PPE providing only limited protection against chemical attack or against ionizing radiation;

(4) - emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material;

(5) - emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50C or less;

(6) - PPE to protect against falls from a height;

(7) - PPE against electrical risks and dangerous voltages or PPE used as insulation in high tension work.

For instance, PPE protecting against falls from a height belongs to Category III, if designed to allow working at a height as well as to support the wearer in case of a fall. An example is equipment used by repair workers on pylons. Equipment to assist in rock climbing is another example.

PPE providing only limited protection against chemical attack or against ionizing radiation needs to be understood that the protection is limited in time. This means that this type of PPE that reduces the potential risk for direct skin contact can only be used for defined time periods as intended by the manufacturer and prescribed in the instructions for safe use.

For PPE against electrical risks, it is commonly understood that voltages of less than 50 V AC or 75 V DC are not normally considered dangerous.

4. ESSENTIAL REQUIREMENTS FOR HEALTH AND SAFETY

PPE to which this Rulebook applies shall be placed on the market and put into service only if, with proper maintenance and use for its intended purpose, PPE meets the **essential health and safety requirements** listed in Annex 1, and if it does not endanger the health or safety of people, domestic animals or property and meets other requirements of the Rulebook.

Therefore, the PPE can be placed on the market and in use only if it complies with all applicable essential requirements for health and safety applicable to the PPE.

PPE and components of PPE which comply with all requirements of the Rulebook and which are properly marked in accordance with the Rulebook, shall be placed on the market and put into service freely without any restrictions.

As an exception, the PPE that does not meet the requirements of the Rulebook may be presented at trade fairs, exhibitions and the like, provided that an appropriate notice is displayed drawing attention to this fact and the prohibition on its acquisition and/or use for any purpose whatsoever until it has been brought into conformity with this Rulebook by the manufacturer or his representative.

As an exception, components for PPE which do not bear the mark of conformity and which are intended to be incorporated in PPE, may be placed on the market provided that they are not essential to satisfactory functioning of PPE.

The Rulebook, in accordance with the EU Directive 89/686 on PPE, provides only the essential requirements for health and safety of PPE, whilst detailed safety and other technical requirements for PPE are listed in Serbian standards which transpose a harmonized (European) standards for PPE.

PPE manufacturer can choose the way in which these requirements will be met, but compliance with the essential requirements for health and safety is mandatory.

Essential requirements for health and safety are laid down to ensure the highest possible level of protection. In practice this means the best compromise between effective protection, comfort and the ability to use PPE in accordance with generally accepted state of the art. These requirements should be applied in accordance with the terms of use for which the PPE is intended.

Annex 1, which contains the essential requirements for health and safety of PPE is divided into three sections:

-General requirements for health and safety that apply to all PPE (principles of design such as ergonomics, safety, comfort, information that must be provided by the manufacturer such as expiry date, storage conditions, the meaning of labels, etc.).;

-Additional requirements common to several classes or types of PPE (e.g. requirements for PPE intended for face protection, eyes and respiratory organs protection, PPE for use in explosive atmospheres) - in this section requirements are defined in connection with class-types of PPE;

-Additional requirements specific for particular risks (e.g., protection from drowning, protection from mechanical impact, protection from harmful noise, etc.) - In this section requirements are defined in relation to the specific risks.

Considering the above, in addition to the general requirements, manufacturers should clearly identify the following:

- Hazards from which PPE shall protect in order to determine additional requirements to be applied to the PPE;

- Anticipated conditions for use of PPE and potential misuse of the product.

Essential requirements for health and safety define the results to be achieved, or the dangers that PPE must fight, but do not say or do not provide technical solutions for this. Also, they are defined in a way as to allow an assessment of compliance with the requirements even in the case of absence of Serbian standards transposing EU harmonized standards, or if the manufacturer decides not to apply the standards.

This flexibility allows manufacturers to choose the most appropriate way to meet the requirements. It also allows, for example, that materials and design of PPE products adapt to technological progress and technical knowledge at any given moment.

If a PPE manufacturer decides to use Serbian standards to comply with the essential requirements for health and safety of the Rulebook, it must be ensured that these standards cover all essential requirements for health and safety applicable to the product, under conditions for use envisaged for specific PPE.

If Serbian standards do not include all essential requirements for health and safety applicable to specific PPE, in addition to the application of these standards, compliance with all applicable essential requirements for health and safety that are not covered by the standard must be evaluated, by using other relevant technical specifications and methods.

5. REFERENCE TO SERBIAN STANDARDS TRANSPOSING EU HARMONIZED STANDARDS

The **Rulebook** is accompanied by the **List of Serbian standards in the field of PPE published in the Official Gazette of RS No. 10/12** in accordance with the law, its bylaws and the Rulebook. These are Serbian standards transposing harmonized (European) standards in the field of PPE.

Implementation of Serbian standards shall presume conformity with relevant health and safety requirements for PPE covered by the standard(s) applied.

To obtain a presumption of conformity, it is necessary for a standard to be published at the List of standards for PPE by the Minister of Economy and Regional Development.

List of standards in the field of PPE published in the Official Gazette of the RS is regularly updated.

Application of a Serbian standard transposing harmonized European standard is always voluntary. This means that even in case when the health and safety requirements are covered by Serbian standards, manufacturer of PPE remains free to apply alternative specifications. The purpose is to prevent technical standards to become an obstacle to innovative technical solutions that were not foreseen when the harmonized standard was drafted.

However, a Serbian standard provides an indication of the state of the art at the time when it was adopted and sets the level of safety and protection which can be reasonably expected for a given type of product at a given time. PPE manufacturer who chooses to apply other technical specifications must be able to show that his solution provides a level of safety that it is at least equivalent to that afforded by the specifications of the Serbian standard.

6. PRESUMPTION OF CONFORMITY

When the reference to a Serbian standard transposing harmonized European standard has been published at the List of Serbian standards for PPE in the Official Gazette of RS, implementation of its specifications confers **a presumption of conformity** with the essential health and safety requirements they cover.

This presumption exists from the date on which the reference of the standard is published in the Official Gazette of RS for the first time (even if the standard is implemented and published at a later date by a national standardization organization).

The presumption of conformity usually ceases when the standard is replaced by a new or revised standard (i.e. presumption exists before the date of cessation of presumption of conformity for the withdrawn/revised standard, that is specified at the List of Serbian standards for PPEin the Official Gazette of RS).

The presumption of conformity conferred by application of a harmonized standard is not absolute, since the conformity of the standard itself can be challenged.

However, a product designed and constructed according to a harmonized standard is presumed to comply with the essential requirements it covers unless proven otherwise.

Thus the manufacturer of PPE who applies a harmonized standard is provided with a measure of legal certainty, since he does not have to provide further evidence of conformity with the essential health and safety requirements covered by the standard.

7. TECHNICAL DOCUMENTATION AND RISK ASSESSMENT

The manufacturer has the obligation to ensure the conformity of PPE that he produces with the relevant essential requirements for health and safety.

The manufacturer or his authorized representative established in Serbia has the obligation to put together technical documentation whatever the category of PPE.

The technical documentation must enable assessment of conformity with the requirements of the Rulebook. The documentation must comprise all relevant data on themeans used by the manufacturer to ensure that a PPE complies with the basic requirements relating to it, including instructions for use with all relevant infomations for PPE.

The manufacturer or his authorized representative must keep the technical documentation and make it available to the surveillance authority upon request at least ten years after the date of manufacturing of PPE or at least ten years after the date of the last specimen manufactured in case of serial production.

In all cases, the manufacturer of PPE **must assess the level of risk from which the targeted user of PPE shall be protected**. The risk assessment is essential for proper classification of PPE, as well as for adequate implementation of relevant provisions of the Rulebook.

If there's no facilities or expertise available the manufacturer can outsource them form a third party. Even in case of third party involved in the process of risk assessment and procedure of conformity assessment, the manufacturer still assumes full responsibility for compliance with the Rulebook.

Upon start of implementation of Directive 89/686 on PPE, series of questions have been reported regarding the classification of PPE into an appropriate category. If the risk is bigger than the one specified, it shall be considered that PPE belongs to a higher category of PPE.

For example, the protection against sunlight is considered to be against indirect solar radiation. This is related to eye protectors and filters without corrective effect designed and manufactured exclusively to provide protection against indirect solar radiation (e.g. sunglasses, that belong to Category 1 PPE).

However, if they are intended to provide additional protection such as against mechanical risks, splashes, molten metal, dust particles, they may be more correctly placed in a higher category.

It is accepted that PPE for direct observation of the sun (e.g. sun eclipses) or against radiation from artificial light sources such as those used in solaria also belong to a higher category.

8. CONFORMITY ASSESSMENT

8.1. Conformity assessment to be carried out by manufacturer of PPE

Conformity with essential requirements of the Rulebook is achieved by stipulating that manufacturer of PPE shall ensure the conformity with all applicable essential requirements for health and safety, and that he must put together technical documentation, issue a declaration of conformity and affix the conformity mark on each PPE.

The obligation to put together technical documentation and issue a declaration of conformity which shall be made available in a defined period of time, as well as the obligation to affix the mark of conformity on each PPE, applies to all categories of PPE.

8.2. Conformity assessment to be carried outby designated CABs

For certain categories of PPE intended for use in higher risk conditions (PPE Category II and PPE Category III) the manufacturer is obliged to ensure that **type examination** of PPE is performed by a designated CAB.

For PPE intended for use in highest risk conditions (PPE Category III), the manufacturer is obliged to apply one of the following two procedures, in addition to type certification: conformity with the type approved based on internal control and **supervised testing of PPE at random intervals** by a designated CAB, **or** ensuring conformity with the type based on **production quality monitoring system** approved by a designated CAB.

It should be noted that **only a single application for an EC-type examination can be made to a single designated conformity assessment body**.In this regard, it is necessary to submit a statement that an application is made only to a single designated conformity assessment body.

The Rulebook stipulates that conformity assessment body conducts or participates in one of the conformity assessment procedures defined in the Rulebook, only if the requirements for designation have been met.

When the Rulebook stipulates that a CAB conducts or participates in one of the conformity assessment procedures, such procedure is performed only by a **designated conformity assessment body** which is registered at the **Register of designated bodies** for the relevant conformity assessment procedure.

Registry data on designated bodies and the scope of designation for each individual body is available on the website of Ministry of economy and regional development:**www.tehnis.merr.gov.rs.**[1]

The choice of a designated conformity assessment body lies on the PPE manufacturer.

In practice, the question appears on how to apply the Rulebook to different variations of PPE (including those adjusted to a specific person who wears it).

In fact, in these cases, the following should be considered:

A PPE is considered as a variant of a "model" PPE only if it differs on points that have no noticeable influence on the expected protective performances.

Careful assessment has to be made by the manufacturer in collaboration with the conformity assessment body.

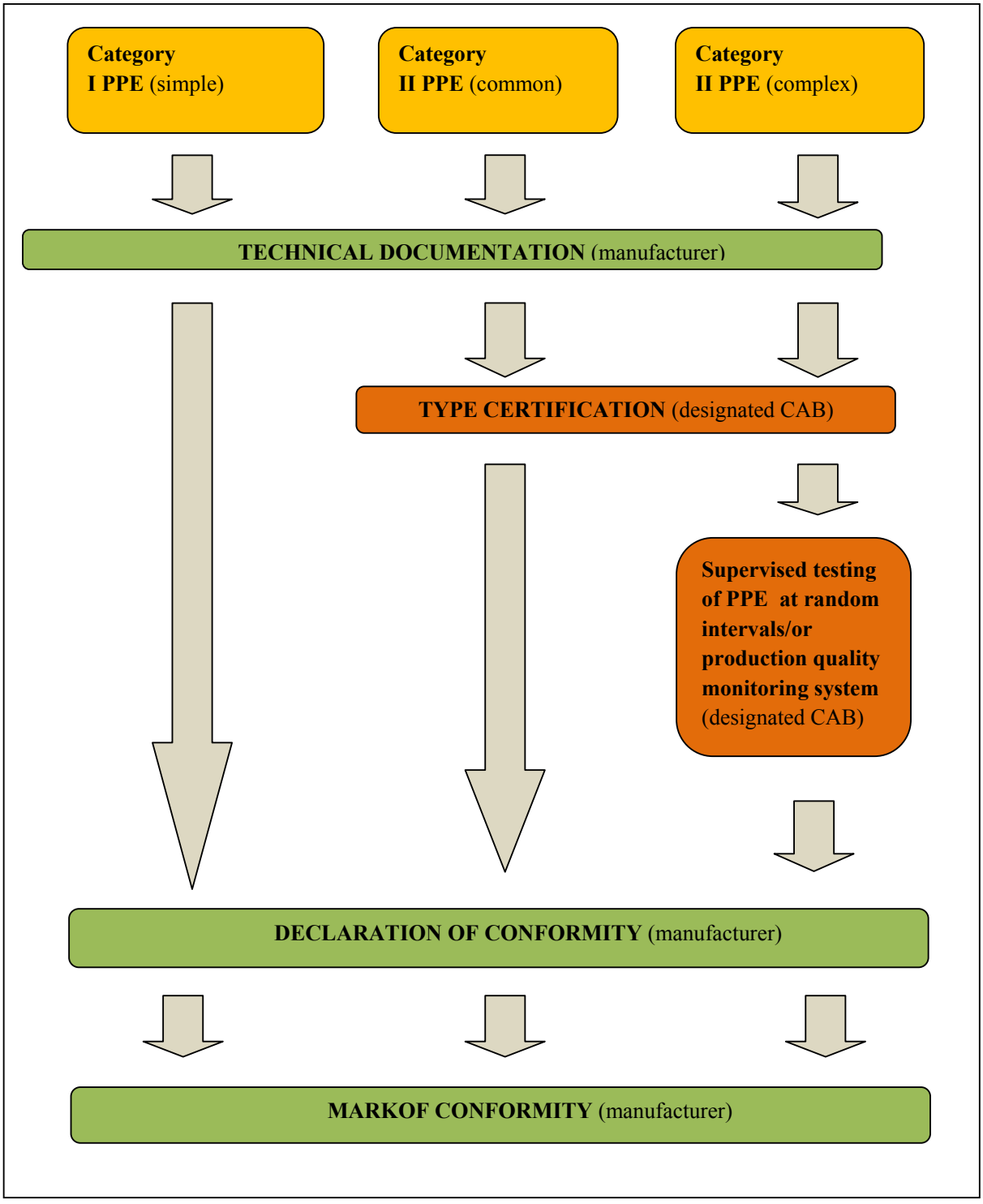
It is the responsibility of the conformity assessment body, on its own authority, to evaluate in each case if a given PPE can be considered as a variant.

In every case and for each of the variants identified, the applicant will provide the CAB with a detailed description indicating the differences in comparison with the reference model and the number of samples of the variants required for complementary checks and tests;

The conformity assessment body is free to decide whether it will grant extensions to existing type examination certificates or if it prefers to issue a new type examination certificate for the variant to be certified.

[1] Due to the change of the name of the Ministry of Economy and Regional Development to the Ministry of Finance and Economy, the new web address will be: www.tehnis.mfp.gov.rs

CONFORMITY ASSESSMENT OF PPE



9. CONFORMITY MARKING AND DOCUMENTATION

9.1. Declaration of conformity

Declaration of conformity shall be issued by a manufacturer or its representative based in Serbia before the PPE is placed on the market or put into service.

The content of the declaration must certify that the PPE complies with all requirements of the Rulebook.

The manufacturer or its representative based in Serbia is solely responsible for issuing a declaration of conformity. Its basic goal is to convince the authorities that PPE placed on the market complies with the essential requirements for health and safety.

Each PPE is not necessarily accompanied by a declaration of conformity, but a supplier must ensure its availability at the request of the authorities.

For all categories of PPE, the declaration of conformity must ensure that PPE meets the essential requirements for health and safety and the text of a declaration must be in compliance with the Rulebook.

It is important to highlight that for PPE Category II and PPE Category III, the declaration of conformity must additionally ensure that PPE is in conformity with the type/model for which the type certificate was issued. Name, address and unique number of the designated CAB that issued the type certificate must be entered in the declaration of conformity, as well as the number of the type certificate issued.

For Category III PPE, the following additional elements must be included in the declaration in the manner stipulated in the Rulebook:

Business name and the address, and the unique number of the designated CAB which performed the testing of samples of PPEin the procedure of product quality controlfollowed by supervised testing in random intervals (the unique number from the Register of designated bodies) and the number of test report, or, where appropriate, business name, address and a unique number of the designated CAB which approved the production quality system (the number from the Register of designated bodies) and the number of a certificate to which the approval refers.

A supplier of PPE shall keep the original copy of the declaration of conformity or its photocopy with translation into Serbian language, if PPE is not produced in Serbia, and it must be available and accessible to the market surveillance authorities at least ten years after the date of manufacturing of PPE or the date when the last specimen of PPE in the case of serial production.

A model of declaration of conformity for PPE is given on the next page.

MODEL OF DECLARATION OF CONFORMITY FOR PPE

DECLARATION OF CONFORMITY FOR PPE

Manufacturer (or his authorized representative in RoS)

.....,

(name and the address of the registered seat of the manufacturer, or his authorized representative in RoS, and if PPE is imported, the name and the address of the legal entity, physical person or entrepreneur in RoS responsible for making available the technical documentation)

hereby declares that PPE ..... (description of PPE – type, serial number, etc)

intended for ..... (intended use),

is in conformity with the requirements of the Rulebook on PPE („Official Gazette of RoS" No. 100/11), as well as with the requirements of .....(list other requirements, if applicable),

and in conformity with the following Serbian standards transposing harmonized standards ..... (list other standards and technical specifications, if applied)

*** that PPE is identical to PPE for which the Type certificate No.....which was issued by ..... (the name and the address of the CAB which issued the Type certificate, as well as the unique registration number of the CAB from the Register of designated CABs),**

**** that PPE undergone a sample testing stipulated in Article 12. of the Rulebook/or, that PPE was subject to quality assurance of the production as stipulated in Article 13. of the Rulebook, carried out by ..... (the name and the address of the CAB which carried out the conformity assessment of PPE, the unique registration number of the CAB from the Register of designated CABs, as well as the number of the conformity document issued by the CAB)**

.....	**…….**
(place and date of issue of declaration)	**(signature/identification of the authorized person of the manufacturer or his authorized representative in RoS)**

***applicable only for PPE Category II and for PPE Category III**

**** applicable only for PPE Category III**

9.2. Certificates and decisions of CABs

Appropriate certificates and decisions must be made by designated bodies in the process of conformity assessment of PPE,in the following cases:

- **Type certificate** in accordance with the procedure for type certification of PPE which must be provided for **both Category II PPE and Category III PPE**,

- **Test reportof the sample of PPEwhich must confirm the compliance of the sample with the type of PPE described in the type certificate** (this report is made in the process of internal production control followed by supervised testing of PPE at random intervals by a designated CAB), for **Category III PPE**, **or**

- Decision on approval of the productionquality system, for Category III PPE.

9.3. Manuals

The supplier who places PPE (Categories I, II or III of PPE) on Serbian market and/or puts them into service, shall **provide instructions for use of PPE together with the PPE, i.e**. i**nformation on the following**:

- The storage, use, cleaning, maintenance, servicing and disinfection of PPE (cleaning products, maintenance or disinfectant recommended by the manufacturer may not have an adverse effect on PPE or users when applied in accordance with relevant instructions),

- Performance recorded during technical tests confirming the level or class of protection provided by PPE tested,

- The appropriate PPE accessories and the characteristics of appropriate spare parts, safety classes corresponding to different levels of risk and relevant restrictions in use,

- The lifetime of PPE and its components,

-Type of packaging suitable for transport of PPE and meaning of markings.

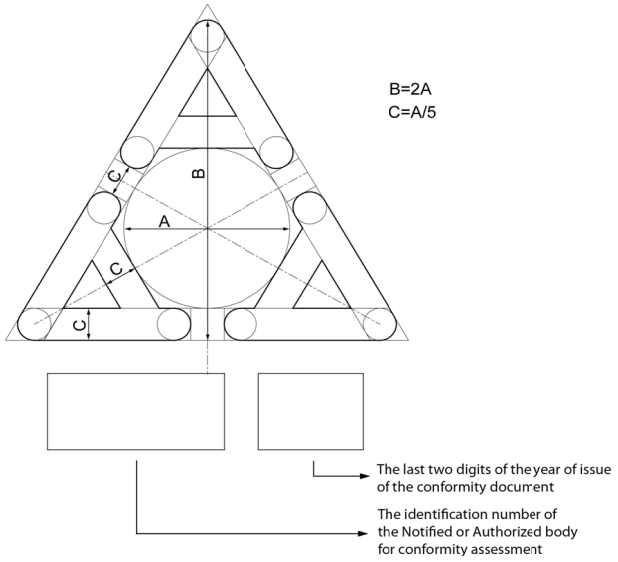
The information must be accurate, comprehensible and given in Serbian language.

9.4. Marking of PPE

PPE which complies with the requirements of the Rulebook, prior to its placing on the market and/or putting into service, shall have affixed the mark of conformity in the manner and form prescribed in the Rulebook.

Conformity mark shall be affixed on the PPE by the manufacturer or its representative in Serbia, or importer if neither the manufacturer nor its representative is registered in Serbia, onto a visible place so as to be visible, legible and indelible during the usage of PPE, in accordance with the regulations governing the manner of placing and use of marks of conformity.

In case where a CAB performed a conformity assessment of PPE in accordance with relevant provisions of the Rulebook, identification number of a designated CAB that participated in the respective conformity assessment procedure shall also be affixed (unique number from the Registry of Designated CABs in Serbia), as well as last two digits of the year of issuing of the conformity document issued by that body (*see the picture below*).



Serbian mark of conformity

10. SAFEGUARD CLAUSE

Supply or use of PPE being placed on the market in Serbia, which meets the requirements of the Rulebook and if used in accordance with the intended use and in conditions that can be reasonably foreseen, with conformity mark affixed on, and accompanied by the declaration of conformityand other prescribed documentation, may be restricted or prohibited in accordance with the law governing the technical requirements for products and conformity assessment.

This means that the surveillance authorities have the right and duty to act within their legal powers when the product is supplied with appropriate documentation and marked in accordance with the regulations, if it turns out that it is not safe or does not comply with the requirements of the Rulebook.

11. MARKET SURVEILLANCE

PPE marked with the conformity mark and supplied with a declaration of conformity is considered to be in conformity with the provisions of the Rulebook. However, market surveillance authorities should ensure that conformity assessment procedures are performed correctly and that the mark of conformity relates to the actual compliance with the essential health and safety requirements of the Rulebook. The new Law on Market Surveillance ("Official Gazette of RoS" No. 92/11) represents, together with the specific regulations in the field of technical legislation, the legal basis for market surveillance and inspection in the field of PPE.

Market surveillance is carried out after manufacturing of PPE, which means at the time of placing on the market of the Republic of Serbia and after placing of PPE on the market.

The competent inspector has the authority to take measures in accordance with the Law on Technical Requirements for Products and Conformity Assessment ("Official Gazette of RoS" No. 36/09), regardless of whethera PPE is provided with a conformity document or not (which includes requiring information and documents from manufacturers and other suppliers, sampling, restriction or prohibition of placing a product on the market, product recall, product withdrawal from the market and, in certain situations, destruction of the product as a last measure).

12. TRANSITIONAL PERIOD (FOR APPLICATION OF OLD LEGISLATION)

The transitional and final provisions of the Rulebook stipulates that the Rulebook shall come into force eight days after its publication in "Official Gazette of the Republic of Serbia". The Rulebook shall be applicable as of 1, July 2013, since the major part of domestic manufacturers and other suppliers of PPE are not able to adjust their capacities and personnel to implement the Rulebook immediately after it's entry into force.

In this regard, it is envisaged that the certificates of conformity issued in accordance with regulations which shall expire on the day of commencement of the application of the Rulebook, are valid until the expiry date in accordance with such regulations, and not later than 1, July 2013.

13. CONCLUSION–OBLIGATIONS OF MARKET OPERATORS DEFINED IN THE RULEBOOK

Market operators affected by the obligations stipulated in the Rulebook are primarily manufacturers of PPE, their representatives in Serbia, as well as importers and distributors of these products. The Rulebook also prescribes provisions relating to the designated conformity assessment bodies.In addition, other companies, governmental bodies and entrepreneurs, are also required to ensure, when making PPE available to the employees in the work process, that such PPE is in conformity with the requirements of the Rulebook.

PPE manufacturers are required to ensure the conformity of PPE with requirements of the Rulebook; to produce technical documentation and ensure that applicable conformity assessment procedure is performed; to produce a declaration of conformity and keep it within the prescribed period; to ensure that the product is supplied with the documentation required and that such documentation is kept within the prescribed period; and that the product is marked in a prescribed manner. All suppliers of these products, including importers and distributors, have the obligation to check whether the product is supplied with a declaration of conformity and marked with a conformity mark, as well as whether it is marked in a manner that allows the identification of the product/manufacturer and provided with required documentation.

RULEBOOK ON PERSONAL PROTECTIVE EQUIPMENT

(Official Gazette of RS, No 100/2011)

I INTRODUCTIORY PROVISIONS

Subject of the Law

Article 1

This Rulebook sets out basic health and safety requirements and other requirements and conditions with which personal protective equipment needs to be compliant before it is placed on the market and/or put into service so as to protect the health and safety of the users of such equipment; categories and types of personal protective equipment; conformity assessment procedures; the content of technical documentation; the content of the declaration of conformity; conformity mark and conformity marking; safeguard clause and requirements to be met by conformity assessment bodies to be notified for the assessment of conformity.

Specific terminology

Article 2

For the purpose of this Rulebook some specific terminology is used, such as:

1) *Personal protective equipment* (hereinafter: PPE) shall mean any equipment (appliance, device, unit, etc.) worn or held by the user to protect himself against one or more health and safety hazards, as well as:

(1) Equipment constituted by several appliances, units, devices, or other components which the manufacturer has integrally combined for the protection of the user against one or more potentially simultaneous risks;

(2) A protective device, unit, or appliance combined, whether or not detachable, with other personal equipment, other than protective equipment, worn or held by the user for the execution of a specific activity;

(3) Interchangeable PPE components which are essential to its proper and correct functioning and used exclusively for such equipment.

Any appliance, unit, or device, namely any system placed on market in conjunction with PPE for its connection to other external additional appliance shall be regarded as an integral part of that PPE even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure

2) *Placing on the market* shall mean the first making available of PPE on the market of the Republic of Serbia for distribution or use, for payment or free of charge;

3) *Manufacturer* shall mean any legal person, entrepreneur, or natural person who manufactures PPE with view to place it on the market under his brand name, trade name, trademark, or other recognisable designation, or for his own private use; or a person who presents himself as the manufacturer of PPE by affixing to the product his business name, trademark, or other recognisable designation, or otherwise. If the manufacturer is unknown, the manufacturer shall be deemed to be any legal person, entrepreneur, or natural person who places PPE on the market and/or puts it into service;

4) *Designated Body* shall mean a body designated to carry out the conformity assessment procedures under this Rulebook;

5) *Authorised representative* shall mean any legal person or entrepreneur established in the Republic of Serbia, or a natural person domiciled in the Republic of Serbia which the manufacturer authorised in writing to, on his behalf, perform all or a part of the obligations laid down in this Rulebook;

6) *Putting into service* shall mean the first use of PPE for its intended purpose in the Republic of Serbia;

7) *Harmonised standard* is a standard adopted by European standardisation organisations, specifically by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI) on the basis of the European Commission ordinance published in the Official Journal of the European Commission.

The terminology used in this Rulebook, other than defined in paragraph 1 of this Article, shall have the meaning as defined in the laws governing technical requirements for products and conformity assessment, general product safety and standardisation.

Application

Article 3

This Rulebook shall apply to all PPE referred to in Article 2 paragraph 1 subparagraph 1) of this Rulebook.

This Rulebook shall not apply to:

1) PPE designed and manufactured specifically for use by armed forces or in the maintenance of law and order (helmets, shields, etc.);

2) PPE for self-defence (aerosol canisters, personal deterrent weapons, etc);

3) PPE designed and manufactured for private use against:

(1) Adverse atmospheric conditions (headgear, seasonal clothing, footwear, etc.);

(2) Damp and water (dish-washing gloves, etc.);

(3) Heat (gloves, etc.).

4) PPE intended for the protection or rescue of persons on vessels or aircraft, not worn all the time, used only as necessary;

5) Helmets and visors intended for users of two- or three- wheeled vehicles.

When the risks related to the use or characteristics of the PPE under this Rulebook are fully or partly covered by relevant legislation, the latter shall apply to those risks.

II PLACING ON THE MARKET AND/OR PUTTING INTO SERVICE

Basic health and safety requirements

Article 4

The PPE under this Rulebook shall be placed on the market and/or brought into service only if, provided it is correctly maintained and used for intended purposes, it meets the basic requirements for health and safety protection referred to in Annex 1 *Basic Health and Safety Requirements for PPE*, printed together with this Rulebook and constituting an integral part thereof, without prejudice to the health or safety of other individuals, domestic animals or goods when other requirements under this Rulebook are met.

Free movement

Article 5

PPE and PPE interchangeable components referred to in Article 2 paragraph 1 subparagraph 1) indent (3) of this Rulebook meeting the requirements and conditions under this Rulebook and having the conformity marking correctly affixed in accordance with this Rulebook, shall be placed on the market and/or brought into service freely, without any restrictions.

By way of an exception, the PPE not meeting the requirements and conditions under this Rulebook may be publicly displayed and shown at trade fairs, exhibitions, presentations and similar events, provided that an appropriate notice is displayed drawing attention to the fact that the PPE in question is not in conformity with the requirements under this Rulebook and the prohibition on its acquisition and use for any purpose whatsoever until it has been brought into conformity by the manufacturer or his authorised representative.

By way of an exception, PPE components intended to be incorporated in PPE, which do not bear the conformity marking, may be placed on the market without any restrictions whatsoever, provided that they are not essential to the satisfactory functioning of the PPE in which they are incorporated.

III PPE CATEGORIES AND TYPES

PPE categories

Article 6

PPE are classified into three categories, specifically:

1) Category I (simple);

2) Category II (neither simple nor complex);

3) Category III (complex).

Category I referred to in paragraph 1 subparagraph 1) of this Article shall cover the PPE for which its manufacturer or his authorised representative assumes that the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time, that is intended to protect the user against:

(1) Mechanical action (gardening gloves, thimbles, etc.) whose effects are superficial;

(2) Cleaning materials of weak action (gloves affording protection against diluted detergent solutions, etc.);

(3) Risks encountered in the handling of hot components which do not expose the user to a temperature exceeding +50°C or to dangerous impacts (gloves, aprons for professional use, etc.);

(4) Atmospheric agents of a neither exceptional nor extreme nature (headgear, seasonal clothing, footwear, etc.);

(5) Minor mechanical impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (light helmets, gloves, light footwear, etc.);

(6) Sunlight (sunglasses).

Category II referred to in paragraph 1 subparagraph 2) of this Article shall cover all PPE other than PPE Category I or PPE Category III.

Category III referred to in paragraph 1 subparagraph 3) of this Article shall cover the PPE intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the manufacturer or his authorised representative assumes the user cannot identify in sufficient time. This category shall cover exclusively:

(1) Filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;

(2) Respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;

(3) PPE providing only limited protection against chemical attack or against ionizing radiation;

(4) Emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material;

(5) Emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less;

(6) PPE to protect against falls from a height;

(7) PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work.

PPE categories

Article 7

The PPE classification into categories referred to in Article 6 of this Rulebook, with marking the category to which particular type of PPE belongs, as laid down in Annex 5 *Categories and Types of PPE*, is printed together with this Rulebook and constitutes an integral part thereof.

Placing on the market and/or bringing into service different PPE categories

Article 8

A PPE may be placed on the market or brought into service in the Republic of Serbia only if it, depending on the category, meets the undermentioned requirements:

1) For PPE Category I:

(1) The PPE is in conformity with relevant basic health and safety requirements referred to in Annex 1;

(2) Accessibility of PPE technical documentation has been ensured in accordance with Annex 2 *Technical Documentation for PPE*, which is printed together with this Rulebook and constitutes an integral part thereof;

(3) The PPE Declaration of Conformity has been drawn up and issued in accordance with Annex 3 *Declaration of Conformity*, which is printed together with this Rulebook and constitutes an integral part thereof;

(4) The conformity marking is affixed to all PPE in accordance with Annex 4 *Conformity Marking*, which is printed together with this Rulebook and constitutes an integral part thereof.

2) For PPE Category II:

(1) The PPE is in conformity with relevant basic health and safety requirements referred to in Annex 1;

(2) Accessibility of PPE technical documentation has been ensured in accordance with Annex 2;

(3) The Designated Body has been provided the PPE sample for type inspection and the conformity assessment process referred to in Article 11 of this Rulebook has been implemented;

(4) Declaration of conformity has been drawn up and issued in accordance with Annex 3;

(5) Conformity marking is correctly affixed to All PPE in accordance with Annex 4.

3) For PPE Category III:

(1)The PPE is in conformity with relevant basic health and safety requirements referred to in Annex 1;

(2) Accessibility of PPE technical documentation has been ensured in accordance with Annex 2;

(3) The Designated Body has been provided the PPE sample for type inspection and the conformity assessment process referred to in Article 11 of this Rulebook has been implemented;

(4) The PPE conformity assessment referred to in Article 12 of this Rulebook or the PPE conformity assessment process referred to in Article 13 of this Rulebook has been implemented;

(5) The Declaration of Conformity has been drawn up and issued in accordance with Annex 3;

(6) The conformity marking is affixed to al PPE in accordance with Annex 4 and the identification number of the Designated Body which has implemented the conformity assessment process referred to in Article 12 or Article 13 of this Rulebook.

The requirements referred to in paragraph 1 of this Article shall not apply to the PPE components intended to be incorporated in PPE, provided that those components are not essential for correct functioning of the PPE in which they are incorporated.

The fulfilment of the requirements referred to in paragraph 1 of this Article shall be the obligation of the manufacturer, or his authorised representative, in accordance with the law governing technical requirements for products and conformity assessment.

By way of an exception, for the PPE that is imported into the Republic of Serbia, the affixing of conformity marking and the providing of samples for type inspection referred to in Article 11 of this Rulebook, may be carried out by the importer of the PPE in question, in accordance with the legislation governing the implementation of conformity assessment and the manner in which conformity marking should be affixed and used.

IV CONFORMITY ASSESSMENT PROCEDURES

Implementation of conformity assessment by the Designated Body

Article 9

The conformity assessment body shall carry out, namely participate in carrying out, one of the PEE conformity assessment processes referred to in Art. 10 to 13 of this Rulebook, provided it meets the requirements for conformity assessment referred to in Annex 6 *Requirements to be met by a conformity assessment body to be designated for conformity assessment*, printed together with this Rulebook and constituting its integral part, and, provided it has been notified in compliance with the law governing technical requirements for products and conformity assessment and the legislation based thereon (hereinafter: the Designated Body).

Conformity assessment processes for different categories of PPE

Article 10

Before starting a serial production of PPE Category II or PPE Category III, the manufacturer or his authorised representative, namely the importer, shall, in accordance with the law governing technical requirements for products and the legislation based thereon, supply a sample of relevant PPE to the Designated Body carrying out the conformity assessment procedure of type examination referred to in Article 11 of this Rulebook.

For PPE Category I, the conformity assessment procedure referred to in paragraph 1 of this Article shall not be needed.

Where PPE Category III is manufactured, the manufacturer shall apply, by his own choice, either the conformity assessment procedure referred to in Article 12 or the conformity assessment process referred to in Article 13 of this Rulebook.

Type examination

Article 11

Type examination is the conformity assessment procedure whereby the Designated Body establishes and certifies that the PPE model in question meets the requirements under this Rulebook.

Application for type examination shall be made to a single Designated Body chosen by the applicant depending on the PPE model to be examined.

The application for type examination shall be submitted in accordance with law and shall comprise:

1) The name and address of the manufacturer or his authorised representative, namely the importer, and the name and address of the production plant, namely the organisational segment or unit in which the PPE in question is manufactured;

2) The manufacturer's technical documentation, in accordance with Annex 2.

The application for type examination shall be submitted to the Designated Body accompanied by the appropriate number of specimens.

The Designated Body shall conduct the type examination in accordance with the undermentioned procedures:

1) Examining the manufacturer's technical documentation;

2) Examining the sample of the product type in question.

Technical documentation referred to in paragraph 5 subparagraph 1) of this Article shall be examined, namely checked, to establish its suitability with respect to applicable Serbian standards from the List of Standards for PPE.

Where a manufacturer has not applied, or has only partly applied, the Serbian standards referred to in paragraph 6 of this Article, or where there are no such standards, the Designated Body must check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements referred to in Annex 1.

By examining the sample of the product type, the Designated Body shall verify that it has been manufactured in accordance with the manufacturer's technical documentation and can be used in complete safety for its intended purpose.

The Designated Body shall perform the necessary examinations and testing to establish the conformity of the type of product with the Serbian standards from the List of Standards for PPE.

Where a manufacturer has not applied, or has only partly applied, the Serbian standards referred to in paragraph 9 of this Article, or where there are no such standards, the Designated Body shall carry out necessary examinations and testing so as to establish the conformity of the model with the technical specifications used by the manufacturer, as well as to establish the suitability of the specifications with the basic requirements referred to in Annex 1.

If the product concerned meets the basic requirements under this Rulebook, the Designated Body shall draw up the Type Examination Certificate and shall notify the applicant to this effect.

The relevant test report must be referred to in the Type Examination Certificate.

Other notified bodies and the competent inspector may obtain a copy of the Type Examination Certificate and, in a response to a reasoned request, a copy of the manufacturer's technical documentation and the reports of the examinations.

The technical documentation shall be held at the disposal of the competent inspectors for minimum 10 years following the PPE manufacturing date or, when PPE is serially produced, ten years after the manufacture date of its last item.

Any Designated Body which refuses to issue a Type Examination Certificate shall inform the other notified bodies of this fact.

A Designated Body withdrawing, or temporarily or permanently revoking, or limiting the validity of the Type Examination Certificate, shall inform the competent inspector and other bodies of this fact in accordance with the law governing technical requirements for products and conformity assessment and the legislation based thereon.

Conformity of the type of product based on internal production control and supervised random checks of the product

Article 12

Necessary steps shall be taken to ensure that the manufacturing process, including the PPE final inspection and testing, ensures the homogeneity of production and the conformity of PPE with the approved type described in the Type Examination Certificate and with the relevant basic requirements under this Rulebook.

The Designated Body, at the request and as chosen by the manufacturer, shall carry out the necessary checks. Those checks shall be carried out at random, normally at intervals of at least one year following the obtaining of the Type Examination Certificate, in order to verify the quality of the internal inspection of products made by the manufacturer.

To check whether the manufactured PPE conforms to the approved type, the Designated Body shall take an adequate sample of the finally produced PPE and conduct testing in accordance with appropriate Serbian standard from the List of Standards for PPE or perform other examinations necessary to prove the conformity with basic health and safety under this Rulebook.

Where the Designated Body conducting the checks at random intervals is not the body that issued the relevant Type Examination Certificate, it shall, in the event of difficulties in connection with the assessment of the conformity of samples, inform the Designated Body that issued the Type Examination Certificate.

The Designated Body which conducted the tests of the sample shall provide the manufacturer with a test report of the sample. If the report concludes that production process is not homogenous with the type described in the Type Examination Certificate or that the PPE examined do not conform to the type described in the Type Examination Certificate or relevant basic health and safety requirements under this Rulebook, the Designated Body shall take appropriate measures and inform the competent inspector accordingly.

On request of the competent inspector, the report issued by the Designated Body which has conducted PPE testing shall be held on his disposal in accordance with law.

Conformity to type based on quality assurance of the production process - production quality assurance

Article 13

Conformity to type based on quality assurance of the production process comprises the quality-control system and checking the conformity of the approved quality-control system by the Designated Body.

The quality-control system referred to in paragraph 1 of this Article must ensure conformity of PPE with the type described in the Type Examination Certificate as well as with the requirements of this Rulebook.

Quality-control system shall comprise the undermentioned activities:

1) The manufacturer of PPE shall apply for the approval of his quality-control system with the Designated Body of his choice, in accordance with the law governing technical requirements for products and the legislation based thereon.

The application referred to in paragraph 1 of this Article shall include:

(1) Business name and address of the manufacturer;

(2) All necessary information relating to the category of PPE concerned;

(3) Written statement of the manufacturer, namely the authorised representative, that no application has been submitted to the same effect with another Designated Body;

(4) Written statement of the manufacturer, namely the authorised representative, that all requirements arising from the quality-control system and their adequacy and efficiency are maintained.

The application referred to in paragraph 1 of this subparagraph shall be accompanied by technical documentation on the type described in the Type Examination Certificate, including the Type Examination Certificate, as well as the documentation relating to quality-control system.

The documentation relating to the quality-control system shall in particular include an adequate description of:

(1) The quality objectives, the organisation chart, the powers and responsibilities of all employees who manage, perform, or verify the activities having impact on product quality;

(2) The checks and tests which must be carried out after manufacture;

(3) The means to be employed to check the efficient operation of the quality-control system.

2) Under the quality-control system, all PPE is inspected and relevant examinations referred to in Article 12 paragraph 3 of this Rulebook are conducted for assessment of conformity with relevant basic health and safety under this Rulebook.

3) The Designated Body shall assess the quality-control system to determine whether the manufacturer correctly meets the provisions arising from the approved quality-control system.

When assessing the quality-control system referred to in paragraph 1 of this Article, the Designated Body shall begin with the presumption that the quality-control system ensures the conformity of PPE with basic requirements under this Rulebook, if in the system in question relevant Serbian standards from the List of Standards for PPE are being applied.

The Designated Body carrying out audits of quality-control systems shall make all necessary assessments of the components of the quality-control system and shall check in particular whether the quality-control system ensures conformity of PPE manufactured with the type described in the Type Examination Certificate.

The Designated Body shall inform the manufacturer, after carrying out the assessment of the latter's quality-control system, about its decision.

The information referred to in paragraph 4 of this Article shall include the conclusions of the check and the reasoned assessment decision.

4) The manufacturer shall inform the Designated Body which approved the quality-control system of any plan to alter the quality-control system. After it receives this information, the Designated Body shall consider the proposed alterations and decide whether the alterations to the quality-control system satisfy the approved quality-control system and shall submit its findings to the manufacturer, including the conclusions of the check and the reasoned assessment decision.

The purpose of the Designated Body checking the conformity of the approved quality-control system referred to in paragraph 1 of this Article is to ensure that a manufacturer correctly fulfils the obligations arising from the approved quality-control system.

In the conformity assessment procedure of the approved quality control system performed by the Designated Body the manufacturer shall provide the Designated Body with access to PPE inspection, testing and storage sites and shall provide all requisite information, in particular:

1) Documentation on quality-control system;

2) Technical documentation;

3) Quality controls manuals.

The Designated Body shall periodically carry out audits to ensure that the manufacturer is maintaining and applying the approved quality-control system and shall provide the manufacturer with a copy of the audit report.

The Designated Body may make unannounced visits to the manufacturer and shall draw up the report on the results which will be submitted to the manufacturer, and, if appropriate, it shall compose the audit report which will also be submitted to the manufacturer.

On the request of the competent inspector, access must be provided to the reports of the Designated Body, issued in the process of assessing the conformity to type based on quality assurance of the production process – production quality assurance, in accordance with law.

V PRESUMPTION OF CONFORMITY

Serbian standards transposing harmonised standards

Article 14

PPE shall be deemed to satisfy the health and safety requirements referred to in Article 4 of this Rulebook if it is manufactured in accordance with Serbian standards for PPE that transposed relevant harmonised standards the list (hereinafter: the List of Standards) of which is composed and published in accordance with the law governing technical requirements for products and conformity assessment and the legislation based thereon.

VI TECHNICAL DOCUMENTATION AND DECLARATION OF CONFORMITY

Technical documentation

Article 15

Technical documentation must facilitate the assessment whether PPE are in conformity with the requirements under this Rulebook.

The manufacturer of PPE shall draw up the technical documentation the contents of which is laid down in Annex 2.

The manufacturer or his authorised representative shall keep technical documentation in accordance with the law governing technical requirements for products, held on disposal of and kept accessible to the competent inspectors at least ten years after the manufacture date of PPE or, when PPE is serially produced, ten years after the manufacture date of its last specimen.

Declaration of Conformity

Article 16

The PPE Declaration of Conformity is a document whereby the manufacturer or his authorised representative certifies that the PPE are in conformity with all requirements under this Rulebook.

The PPE manufacturer or his authorised representative draws up the PPE declaration of conformity, the contents of which is laid down in Annex 3.

The PPE supplier keeps the original declaration of conformity or its copy accompanied by the translation into the Serbian language, where PPE was not manufactured in the Republic of Serbia, and it shall be held on disposal of and kept accessible to the competent inspector for a period of at least ten years after the PPE manufacture date or, when PPE is serially produced, ten years after the manufacture date of its last item.

VII CONFORMITY MARK

Conformity marking

Article 17

The conformity mark shall be affixed to PPE which is in conformity with the requirements under this Rulebook in a way and in a form laid down in Annex 4, before it is placed on the market and/or put into service..

Conformity mark shall be affixed to PPE by the manufacturer or his authorised representative, namely by the importer if the manufacturer or his authorised representative is not established in the territory of the Republic of Serbia, at a visible place so as to be legible and indelible throughout the expected life of PPE, in accordance with the legislation governing the manner in which conformity marking should be affixed and used.

If the Designated Body has implemented the conformity assessment or has participated in that assessment in accordance with Article 11 or Article 12 of this Rulebook, the conformity mark referred to in Section 1 of Annex 4 shall be added the identification number of that Designated Body and the year in which the conformity mark was affixed.

If the Designated Body has implemented the conformity assessment or has participated in that assessment in accordance with Article 11 or Article 12 of this Rulebook, the conformity mark referred to in Article 2 of Annex 4 shall be added the identifying number of that Designated Body and last two digits of the year in which that body issued the conformity document.

Other marks, symbols, texts or other designations may be affixed to PPE, provided they do not compromise the visibility, legibility and/or meaning of the conformity mark.

Other marks, symbols, texts, or other designations may not be affixed to PPE if their affixing is forbidden by the law that governs technical requirements for products and conformity assessment.

If a PPE is subject to other regulations that govern other issues and thus lay down the affixing of conformity mark, the affixed conformity mark shall demonstrate that PPE is in compliance with the requirements of those other regulations.

Unduly marking

Article 18

Unduly marking of PPE shall be deemed to be the affixing of a mark, symbol, text, or other designation the affixing of which is forbidden by the law governing technical requirements for products and conformity assessment, as well as:

1) the affixing of conformity mark to a PPE to which this Rulebook is not applicable;

2) the absence of conformity mark from a PPE which is in conformity with the requirements from this Rulebook.

The affixing and use of the conformity mark, and other marks, symbols, texts, or other designations, shall be performed in accordance with the law that governs technical requirements for products and conformity assessment.

Documentation accompanying the PPE when it is placed on the market and/or put into service

Article 19

A supplier placing the PPE Category I, II, or III on the market of the Republic of Serbia and/or into service, shall have that PPE accompanied by the instructions for use in the Serbian language.

In addition to the instructions referred to in paragraph 1 of this Article, the supplier who is supplying the PPE Category I to the market of the Republic of Serbia shall provide for that equipment an original copy

of the Declaration of Conformity or its photocopy with the translation into the Serbian language, where that equipment is not manufactured in the Republic of Serbia.

A supplier who is supplying the PPE referred to in paragraph 2 of this Article to the market of the Republic of Serbia may have the original Declaration of Conformity, or the translation of that Declaration into the Serbian language where that equipment is not manufactured in the Republic of Serbia, made available on its official website, provided the website address is indicated in the instructions for use of the electric equipment.

In addition to the instructions for use in the Serbian language and the Declaration of Conformity a supplier placing PPE Category II or Category III on the market of the Republic of Serbia and/or putting it into service, shall have PPE accompanied by a corresponding conformity document issued by the Designated Body in accordance with this Rulebook, particularly when Serbian standards from the List of Standards were not applied or were only partly applied in the manufacturing of that PPE, or could not be applied considering that they do not exist.

VIII SAFEGUARD CLAUSE

Safeguard clause

Article 20

The supply or use of the PPE placed on the market of the Republic of Serbia, where it satisfies the requirements under this Rulebook, to which conformity marking was affixed and which is accompanied by the Declaration of Conformity and/or other suitable document of conformity referred to in Article 11 or Article 12 of this Rulebook, used in accordance with intended purpose or under reasonably foreseeable circumstances, may be restricted or prohibited in accordance with the law governing technical requirements for products and conformity assessment.

Conformity with EU legislation

Article 21

This Rulebook is in compliance with all principles and basic requirements under the European Council Directive 89/686 EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment as amended under Directive 93/68/EEC of 22 July 1993, Directive 93/95/EEC of 29 October 1993, and Directive 96/58/EEC of 3 September 1996.

IX TRANSITIONAL AND FINAL PROVISIONS

Article 22

Beginning with the coming into force date of the ratified international agreement on conformity assessment and the acceptance of industrial products (ACAA Agreement) with the EU, in this Rulebook, regarding the PPE to which this Rulebook is applicable, the expression: ‘conformity marking’ in Art. 1, 5, and 8, in the caption of Chapter VII of this Rulebook and in Art. 17 and 18 of this Rulebook, shall mean: ‘CE marking’, and the expression ‘Declaration of Conformity’ in Art. 1 and 8 of this Rulebook, in the caption of Chapter VI of this Rulebook, in the caption of Article 16, an in Articles 16 and 19 of this Rulebook, as well as in Annex 3, shall mean: ‘EC Declaration of Conformity’.

If the Agreement referred to in paragraph 1 of this Article is not concluded, the meaning of the expressions: ‘conformity marking’ and ‘Declaration of Conformity’ referred to in paragraph 1 of this Article shall apply from the day of the accession of the Republic of Serbia to the European Union.

Article 23

Beginning with the coming into force of this Rulebook until the coming into force date of the ratified international agreement referred to in Article 22 of this Rulebook, for the PPE to which this Rulebook is applicable the conformity marking shall be made by affixing the Serbian conformity mark in accordance with this Rulebook and relevant legislation.

If the agreement referred to in paragraph 1 of this Article is not concluded, the conformity marking of PPE shall be carried out by affixing the Serbian conformity mark before the Republic of Serbia's accession date to the European Union.

Beginning with the coming into force date of the ratified international agreement referred to in paragraph 1 of this Article, for the PPE to which this Rulebook is applicable the conformity marking shall be made by affixing the CE mark in accordance with this Rulebook and relevant legislation.

If the agreement referred to in paragraph 3 of this Article is not concluded, the conformity marking of PPE by affixing the CE mark shall be carried out from the Republic of Serbia's accession date to the European Union.

Article 24

With the commencement date of this Rulebook, the following shall cease to apply:

1) Ordinance on mandatory testing and certification of helmets for industrial use (Official Gazette of SFRY, Nos 4/82 and 43/82);

2) Ordinance on mandatory testing and certification of fireman helmets (Official Gazette of SFRY, No 67/86);

3) Ordinance on mandatory testing and certification of protective equipment for the respiratory system (Official Gazette of SFRY, No 49/87);

4) Rulebook on mandatory testing and certification of climbers for wooden electric columns and the requirements to be satisfied by the organisations authorised for the testing and certification of those products (Official Gazette of SFRY, No 67/89);

5) Rulebook on mandatory testing and certification of protective belts and the requirements to be satisfied by the organisations authorised for the testing and certification of those products (Official Gazette of SFRY, No 67/89);

6) Rulebook on technical and other requirements for fireman helmets (Official Gazette of RS, No 74/09);

7) Rulebook on technical and other requirements for personal protective equipment (Official Gazette of RS, No 56/09), with the exception of the provision of Article 2 subparagraph 10) of this Rulebook, relating to the helmets and visors for the drivers of two or three-wheel motor vehicles.

The validity period of the conformity document issued based on the legislation referred to in paragraph 1 of this Article shall subsist until the expiry of the validity period of the document in accordance with those regulations, and shall not exceed 1 July 2013.

Article 25

This Rulebook shall come into force on the 8th day after its publication in the Official Gazette of the Republic of Serbia and it shall start to apply beginning with 1 July 2013.

BASIC HEALTH AND SAFETY REQUIREMENTS

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against all risks encountered.

1.1 Design principles

1.1.1 Ergonomics

PPE must be so designed and manufactured that in the foreseeable conditions of use for which it is intended the user can perform the activity normally whilst enjoying the highest possible level of protection.

1.1.2 Levels and classes of protection

1.1.2.1 Highest level of protection possible

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE would prevent its effective use during the period of the exposure to the risk of normal performance of the activity.

1.1.2.2 Classes of protection appropriate to different levels of risk

Where differing conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

1.2 Innocuousness of PPE

1.2.1 Absence of risks and other nuisance factors

PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

1.2.1.1 Suitable PPE materials

PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.

1.2.1.2 Characteristics of the surface of all PPE parts in contact with the user

Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

1.2.1.3 Maximum permissible user impediment

Any impediment caused by PPE to movements to be made, postures to be adopted and sensory perception must be minimised.

PPE may not cause movements which endanger the user or other persons.

1.3 Comfort and efficiency

1.3.1 Adaptation of PPE to user morphology

PPE must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, movements to be made and postures to be adopted.

It must be possible to optimise PPE adaptation to user morphology by adequate adjustment and attachment systems or the provision of an adequate size range.

1.3.2 PPE lightness and design strength

PPE must be as light as possible without prejudicing design strength and efficiency

Apart from the additional basic requirements referred to in paragraph 3 of this Annex, PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

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

If the same manufacturer markets several PPE models of different classes or types in order to ensure the simultaneous protection of adjacent parts of the body against combined risks, these must be compatible.

1.4 Information supplied by the manufacturer

In addition to the name and address of the manufacturer and/or his authorised representative, the written information that must be supplied when PPE is placed on the market must include:

a) storage, use, cleaning, maintenance, serviceing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;

b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;

c) suitable PPE accessories and the characteristics of appropriate spare parts

d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;

e) the obsolence deadline or period of obsolescence of PPE or certain of its components;

f) the type of packaging suitable for transport;

g) the significance of any markings (in accordance with paragraph 2.12 of this Annex).

The information referred to in paragraph 1 of this Section must be precise and comprehensible and must be provided in the Serbian language.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL CLASSES OR TYPES OF PPE

2.1 PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be so designed and manufactured as not to become incorrectly adjusted without the user's knowledge under the foreseeable conditions of use.

2.2 PPE 'enclosing' the parts of the body to be protected

As far as possible, PPE 'enclosing' the parts of the body to be protected must be sufficiently ventilated to limit perspiration resulting from use; if this is not the case, it must if possible be equipped with devices which absorb perspiration.

2.3 PPE for the face, eyes and respiratory tracts

PPE for the face, eyes and respiratory tracts must be such as to ensure that any restriction of the user's field of vision or sight is minimised.

The degree of optical neutrality of the vision systems of these PPE classes must be compatible with the type of relatively meticulous and/or prolonged activities of the user.

If necessary, PPE must be treated or provided with facilities to prevent moisture formation.

PPE models intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

2.4 PPE subject to ageing

If it is known that the design performances of new PPE may be significantly affected by aging, the date of manufacture and/or, if possible, the date of obsolence, must be indelibly inscribed on every PPE item or interchangeable component placed on the market in such a way as to preclude any misinterpretation. This information must also be indelibly inscribed on the packaging.

If a manufacturer is unable to give an undertaking with regard to the useful life of PPE, his notes must provide all the information necessary to enable the purchaser or user to establish a reasonable obsolescence date, bearing in mind the quality of the model and the effective conditions of storage, use, cleaning, servicing, and maintenance.

Where the cleaning process recommended by the manufacturer may cause the aging and rapid deterioration in PPE performance, the manufacturer must, if possible, affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Failing that, the manufacturer must give this information in his notes.

2.5 PPE which may be caught up during use

Where the foreseeable conditions of use include in particular the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must possess an appropriate resistance threshold above which a constituent part will break and eliminate the danger.

2.6 PPE for use in explosive atmospheres

PPE intended for use in explosive atmospheres must be so designed and manufactured that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.7 PPE intended for emergency use or rapid installation and/or removal

The PPE intended for emergency use or rapid installation and/or removal must be so designed and manufactured as to minimise the time required for attachment and (or) removal.

Any integral systems permitting correct positioning on, or removal from, the user must be susceptible of rapid and easy operation.

2.8 PPE for use in very dangerous situations

The PPE referred to in Article 6 paragraph 1 subparagraph 3) of this Rulebook must include, in particular, the data supplied by the manufacturer that are intended for the exclusive use of competent trained individuals who are qualified to interpret them and ensure their application by the user.

The data referred to in paragraph 1 of this Section must, among other things, describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

If PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be so designed and accommodated as to be perceived by the user in the conditions of use for which the PPE is marketed.

2.9 PPE incorporating components which can be adjusted or removed by the user

Any PPE components which can be adjusted or removed by the user for the purpose of replacement must be so designed and manufactured as to facilitate adjustment, attachment and removal without tools.

2.10 PPE for connection to another, external complementary device

If PPE incorporates a system permitting connection to another, complementary, device, the attachment mechanism must be so designed and manufactured as to enable it to be mounted only on appropriate equipment.

2.11 PPE incorporating a fluid circulation system

If PPE incorporates a fluid circulation system, the latter must be so chosen, or designed, and incorporated as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of user gestures, posture or movement under the foreseeable conditions of use.

2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of PPE must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE.

In addition, the marks referred to in paragraph 1 of this Section must be complete, precise and comprehensible so as to prevent any misinterpretation.

When the marks referred to in paragraphs 1 and 2 of this Section incorporate words or sentences, the latter must appear in the Serbian language

If PPE (or a PPE component) is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's user manual.

2.13 PPE in the form of clothing capable of signalling the user’s presence

PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means of or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

2.14 ‘Multi-risk’ PPE

All PPE designed to protect the user against several potentially simultaneous risks must be so designed and manufactured as to satisfy, in particular, the basic requirements specific to each of those risks (in accordance with Section 3 of this Annex).

3.1 Protection against mechanical impact

3.1.1 Impact caused by falling or projecting objects and collision of parts of the body with an obstacle

Suitable PPE for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the absorbing device would preclude effective use of the PPE for the foreseeable period of wear.

3.1.2 Falls

3.1.2.1 Prevention of falls due to slipping

The outsoles for footwear designed to prevent slipping must be so designed, manufactured or equipped with added elements as to ensure satisfactory adhesion by grip and friction having regard to the nature or state of the surface.

3.1.2.2 Prevention of fall from height

PPE designed to prevent falls from a height or their effects must incorporate a body harness and an attachment system which can be connected to a reliable anchorage point.

It must be designed so that under the foreseeable conditions of use the vertical drop of the user is minimized to prevent collision with obstacles and the braking force does not, however, attain the threshold value at which physical injury or the tearing or rupture of any PPE component which might cause the user to fall can be expected to occur.

PPE referred to in paragraph 1 of this Section must also ensure that after braking the user is maintained in a correct position in which he may await help if necessary.

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

— the characteristics required for the reliable anchorage point and the necessary minimum clearance below the user,

— the proper way of putting on the body harness and of connecting the attachment system to the reliable anchorage point.

3.1.3 Mechanical vibrations

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

Under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.

3.2. Protection against (static) compression of part of the body

PPE designed to protect part of the body against (static) compressive stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.

3.3 Protection against physical injury (abrasion, perforation, cuts, bites)

PPE constituent materials and other components designed to protect all or part of the body against superficial injury caused by machinery, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these PPE classes provide sufficient resistance to abrasion, perforation and gashing (in accordance with Section 3. 1 of this Annex) under the foreseeable conditions of use.

3.4 Prevention of drowning (lifejackets, armbands and lifesaving suits)

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to his health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping him afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated either by gas which can be manually or automatically released or orally.

Under the foreseeable conditions of use:

— PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium,

— inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

— it must have all the inflation devices referred to in the second subparagraph of this paragraph, and/or a light or sound-signalling device,

— it must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium,

— it must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring his immersion in it.

3.4.1 Buoyancy aids

Buoyancy aids are the clothing which will ensure an effective degree of buoyancy, depending on its foreseeable use, which is safe when worn and which affords positive support in water.

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

3.5 Protection against the harmful effects of noise

PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent sound levels perceived by the user do not under any circumstances exceed the daily limit values laid down in relevant legislation governing the protection of workers from the risks related to exposure to noise at work.

All PPE must bear labelling indicating the noise attenuation level and the value of the comfort index provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.

3.6 Protection against heat and/or fire

PPE designed to protect all or part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to foreseeable conditions of use.

3.6.1 PPE constituent materials and other components

Constituent materials and other components suitable for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the outside of the materials and components referred to in paragraph 1 of this Section must be reflective, its reflective power must be appropriate to the intensity of the heat flux due to radiation in the infra-red range.

Materials referred to in paragraph 1 of this Section and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as large quantities of molten material, in addition to the characteristics referred to in paragraphs 1 and 2 of this Section, must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his PPE.

PPE materials and other components which may be splashed by large amounts of hot products must also possess sufficient mechanical-impact absorbency (in accordance with Section 3.1 of this Annex).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment must also possess a degree of non-flammability corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

3.6.2 Complete PPE ready for use

Under the foreseeable conditions of use:

1. the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;

2. PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, their design must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, the latter must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's notes accompanying each PPE model intended for brief use in high-temperature environments must in particular provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

3.7 Protection against cold

PPE designed to protect all or part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is marketed.

3.7.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use.

Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by large amounts of cold products must also possess sufficient mechanical-impact absorbency (in accordance with Section 3.1 of this Annex).

3.7.2 Complete PPE ready for use

Under the foreseeable conditions of use:

1. the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health-impairment threshold;

2. PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

If PPE incorporates a breathing device, this must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's notes accompanying each PPE model intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

3.8 Protection against electric shock

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of these PPE classes must be so chosen or designed and incorporated as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimized and, at all events, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be under tension must bear markings indicating, in particular, their protection class and (or) corresponding operating voltage, their serial number and their date of manufacture; a space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.

The manufacturer's notes must indicate, in particular, the exclusive use for which these PPE types referred to in paragraph 3 of this Section are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

3.9 Radiation protection

3.9.1 Non-ionising radiation

PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To ensure the protection referred to in paragraph 1 of this Section, protective glasses must be so designed and manufactured as to possess, for each harmful wave, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value.

In addition to the requirements referred to in paragraph 2 of this Section, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed items must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's notes must indicate, in particular, the transmission curves

which make it possible to select the most appropriate PPE bearing in mind such inherent factors of the effective conditions of use as distance to source and the spectral distribution of the energy radiated at that distance.

The relevant protection-factor number must be marked on all specimens of filtering glasses by the manufacturer.

3.9.2 Ionising radiation

3.9.2.1 Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof must be so chosen or designed and incorporated as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurization systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible re-use during the foreseeable useful life of these classes of equipment

3.9.2.2 Limited protection against external radiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e. g. beta) or weak photon (e. g. X, gamma) radiation.

The constituent materials and other components of these PPE classes referred to in paragraph 1 of this Section must be so chosen or designed and incorporated as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (in accordance with Section 1.3.2 of this Annex).

PPE must bear a mark indicating the type and thickness of the constituent material(s) suitable for the foreseeable conditions of use.

3.10 Protection against dangerous substances and infective agents

3.10.1 Respiratory protection

PPE intended for the protection of the respiratory tract must make it possible to supply the user with breathable air when the latter is exposed to a polluted atmosphere and/or an atmosphere having inadequate oxygen concentration.

The breathable air supplied to the user by the PPE must be obtained by appropriate means, for example after filtration of the polluted air through the protective device or appliance or by a piped supply from an unpolluted source.

The constituent materials and other components of the PPE classes referred to in paragraph 1 of this Section must be so chosen or designed and incorporated as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must be such as to keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE referred to in paragraph 1 of this Section must bear the manufacturer's identification mark and details of the specific characteristics of that type of equipment which, in conjunction with the instructions for use, will enable a trained and qualified user to employ the PPE correctly.

The manufacturer's notes must also in the case of filtering devices, indicate the deadline for the storage of filters as new and kept in their original packaging.

3.10.2 Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with dangerous substances and infective agents must be capable of preventing the penetration or diffusion of such substances through the protective integument under the foreseeable conditions of use for which the PPE is placed on the market.

The constituent materials and other components of these PPE classes referred to in paragraph 1 of this Section must be so chosen, or designed and incorporated as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain dangerous substances or infective agents possess high penetrative power which limits the duration of the protection provided by the PPE referred to in paragraph 1 of this Section, the latter must be subjected to standard tests with a view to their classification on the basis of efficiency.

PPE referred to in paragraph 3 of this Section which is considered to be in conformity with the test specifications must bear a mark indicating, in particular, the names or, failing this, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's notes must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wearing under the different foreseeable conditions of use.

3.11 Safety devices for diving equipment

1. Breathing equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

2. Where the foreseeable conditions of use so require, diving equipment must comprise:

a) a suit which protects the user against the pressure resulting from the depth of immersion (in accordance with Section 3.2 of this Annex) and/or against cold (in accordance with Section 3.7 of this Annex);

b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (in accordance with Section 2.8 of this Annex);

c) a life-saving suit enabling the user to return to the surface (in accordance with Section 3.4.1 of this Annex).

ANNEX 2

TECHNICAL DOCUMENTATION FOR PPE

The documentation referred to in Article 8 of this Rulebook must comprise all relevant data on the means used by the manufacturer to ensure that a PPE complies with the basic requirements relating to it.

In the case of PPE models referred to in Article 8 paragraph 1 indents 2) and 3) of this Rulebook, the documentation must comprise in particular:

1. The manufacturer's technical documentation consisting of:

overall and detailed plans of the PPE accompanied, where appropriate, by calculation notes and the results of prototype tests in so far as necessary for the verification of compliance with the basic requirements;

an exhaustive list of the basic safety requirements and of the harmonized standards or other technical specifications referred to in Articles 3 and 5, taken into account in the design of the model;

2. A description of the control and test facilities to be used in the manufacturer's plant to check compliance of production PPE with the Serbian standards referred to in Article 14 of this Rulebook or other technical specifications and to maintain quality level;

3. A copy of the information notice referred to in Section 1.4 of Annex 2.

ANNEX 3

DECLARATION OF CONFORMITY

The PPE declaration of conformity shall include the following information:

1) Business name and address of the manufacturer and, when applicable, his authorised representative;

2) Business name and address of the legal person, namely the name of the entrepreneur or natural person, established, namely domiciled in the Republic of Serbia, responsible to ensure the accessibility of technical documentation;

3) Description of PPE, including the general term, function, model, type, serial number, trade name, etc.;

4) Explicit indication that the PPE described in Section 3) of this Annex is in conformity with the under this Rulebook, indicating its full name and the number of the official gazette in which the rulebook in question was published, as well as, when appropriate, indication of conformity with other relevant legislation and/or requirements with which the equipment in question is in conformity;

5) When appropriate, business name, address and identification number of the Designated Body which has conducted the type examination referred to in Article 11 of this Rulebook and the number of the Type Examination Certificate, as well as explicit indication that the PPE described in Section 3) of this Annex is identical to the PPE type to which the Type Examination Certificate applies;

6) when appropriate, business name, address, and identification number of the Designated Body which has conducted the sample test referred to in Article 12 of this Rulebook and the test report number;

7) when appropriate, the business name, address, and identification number of the Designated Body which approved the quality-control referred to in Article 13 of this Rulebook and the document number by which the relevant approval was made;

8) reference to the applied Serbian standards referred to in Article 14 of this Rulebook;

9) when appropriate, reference to other standards and technical specifications if they were applied;

10) declaration place and date of issue;

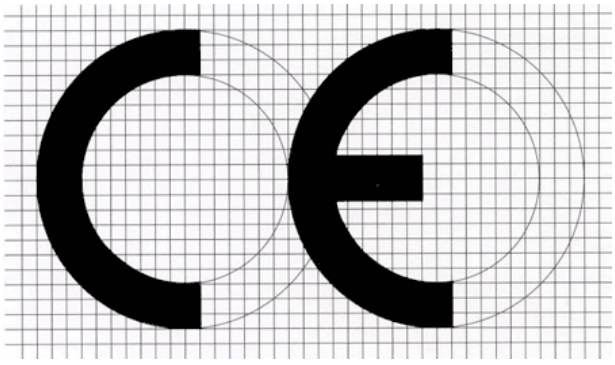
11) name and signature of duly authorised officer, officer responsible to draw up the declaration of conformity on behalf of the manufacturer or his authorised representative.

ANNEX 4

CONFORMITY MARKING

1. CE CONFORMITY MARK

CE conformity mark shall consist of the initials ‘CE’ taking the following form:



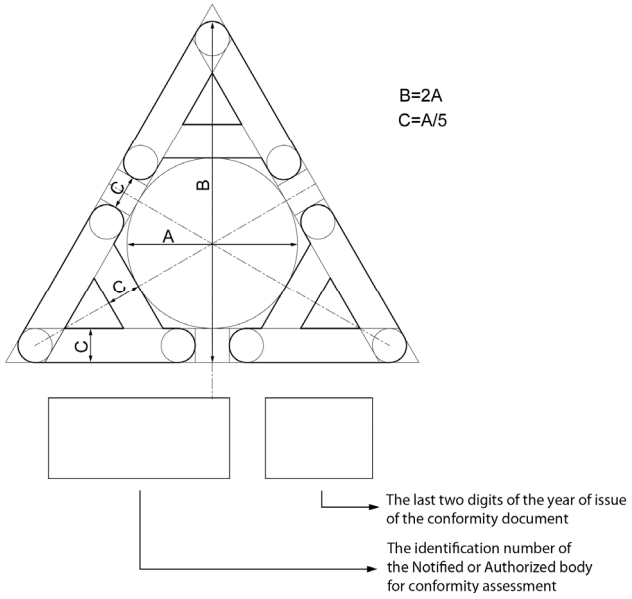
Different components of CE conformity mark must have substantially the same vertical dimension, which may not be less than 5 mm.

If the CE conformity mark is reduced or enlarged the proportions given in the graduated drawing given in paragraph 1 of this Section must be respected.

The CE conformity mark must be affixed to PPE; if this is impossible due to PPE type or characteristics, however, this mark must be affixed to the packaging, if PPE possesses it, or to the accompanying notes.

2. SERBIAN CONFORMITY MARK

Serbian conformity mark consists of three capital letters ‘A’ interconnected in the form of an equilateral triangle (3A), having the appearance and content as shown in the drawing:



The mark shall be determined dimensions by the height of 'V' mark which may only have values of standard numbers rounded up, to the order of magnitude R10 expressed in millimetres (mm) as per Serbian standard SRPS A.A0.001 – Standard Numbers, Numerical Values and Definitions.

As a rule, 'V' mark shall be at least 5 mm high.

Serbian conformity mark shall be accompanied by the identification number of the Designated Body from the register of notified or authorised conformity assessment bodies and by the last two digits of the year of issue of the conformity document, where the mentioned body has implemented, or participated in the implementation of, the conformity assessment.

PPE CATEGORIES AND TYPES

1. PPE FOR HEARING PROTECTION

TYPE OF PPE	CATEGORY
1.1 All equipment protecting hearing (whether worn in or over the ear)	II

2. PPE FOR EYE PROTECTION

TYPE OF PPE	CATEGORY
2.1 All eye protectors and filters	II
2.2 Eye protectors and filters designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
2.3 Eye protectors and filters designed and manufactured to provide protection against ionising radiation	III
2.4 Eye protectors and filters designed and manufactured to provide protection against electrical risks	III
2.5 Swimming and/or diving goggles and masks	I
2.6 Eye protectors and filters designed and manufactured exclusively to provide protection against sunlight, sun glasses (not corrective) for private and professional use. This includes cases where glasses are tinted after manufacturing or any other assembly after manufacturing (e.g. assembly of sunlight protective lenses in a non CE marked frame)	I
2.7 Ski goggles of all types, except corrective spectacles	I

3. PPE FOR PROTECTION AGAINST FALLS FROM A HEIGHT

TYPE OF PPE	CATEGORY
3.1 All protective equipment designed and manufactured to provide protection against falls from a height, for private or professional use (working at heights, falling off boats, mountaineering, rock climbing, speleology, etc.). This category also includes equipment for working at a height and with support (harnesses, thigh straps, belts, etc.) Note: this equipment includes harnesses (thigh straps, shoulder belts, etc.) and all accessories intended for attaching a person to a structure, with the exception of anchorage points forming an integral part of the structure or rock face. - For example: for professional use: lanyards, mobile fall arresters, karabiners, energy absorbers, connectors, anchor points, etc. - For mountaineering, rock climbing, and speleology: connectors (simple ropes), ropes for abseiling (double ropes), slings, climbing karabiners, rope clamps, chocks, pitons, ice pitons, gripping devices for use on artificial climbing walls, etc. Note: the categorisation is not influenced by the fact that the equipment is factory made/assembled or produced/assembled by the (employer) user himself (e.g. double lanyards).	III

4. PPE FOR HEAD PROTECTION

TYPE OF PPE	CATEGORY
4.1 All helmets, including sports helmets	II
4.2 Helmets designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
4.3 Helmets designed and manufactured to provide protection against electrical risks	III
4.4 Light headgear designed and manufactured to provide scalp protection	I

5. PPE FOR PART OR WHOLE FACE PROTECTION

TYPE OF PPE	CATEGORY
5.1 All equipment	II
5.2 Equipment designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100°C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
5.3 Equipment designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less	III
5.4 Equipment designed and manufactured to provide protection against electrical risks	III

6. PERSONAL PROTECTIVE CLOTHING

TYPE OF PPE	CATEGORY
6.1 All items of clothing and/or accessories (whether or not detachable) designed and manufactured to provide specific protection Remark: this category includes also: protective clothing used for sports activities such as diving suits, protective clothes for waterskiing, etc.; bullet-proof clothing used by other than the armed forces (for instance security guards); clothing protecting against infective agents used by other than the armed forces.	II
6.2 Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks	III
6.3 Clothing and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
6.4 Clothing and/or accessories (whether or not detachable) designed and manufactured	III

for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less	
6.5 Clothing and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or against ionising radiation	III
6.6 Clothing and/or accessories (whether or not detachable) designed and manufactured to provide complete insulation from the atmosphere	III
6.7 Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for professional use	I
6.8 Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial	I
6.9 Clothing and/or accessories (whether or not detachable) designed and manufactured to provide protection against risks arising from handling hot components which do not expose the user to a temperature of over 50 °C or to dangerous impacts	I

7. RESPIRATORY PROTECTIVE CLOTHING

TYPE OF PPE	CATEGORY
7.1 All respiratory protective equipment: - designed and manufactured to provide protection against solid aerosols, liquid aerosols or gases; - designed and manufactured to provide full insulation from the atmosphere; - designed and manufactured for use in diving	III

8. PPE F CLOTHINGR LEG AND/OR FOOT AND ANTI-SLIP PROTECTION

TYPE OF PPE	CATEGORY
8.1 All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the foot and/or the leg and to provide anti-slip protection	II
8.2 Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks for work involving dangerous voltages, or used to provide insulation against high voltages	III
8.3 Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material	III
8.4 Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less	III
8.5 Equipment and/or accessories (whether or not detachable) designed and	III

manufactured to provide only limited protection against chemical attack or ionising radiation	
8.6 Sports equipment (in particular sport shoes) and/or accessories (whether or not detachable) designed and manufactured to protect against external impacts	I
8.7 Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against weather conditions which are neither exceptional nor extreme, for professional use	I

9. PPE FOR HAND AND ARM PROTECTION

TYPE OF PPE	CATEGORY
9.1 All equipment and/or accessories (whether or not detachable) designed and manufactured specifically to protect the arm and/or the hand).	II
9.2 Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against electrical risks for work involving dangerous voltages, or used to provide insulation against high voltages	III
9.3 Equipment and/or accessories (whether or not detachable) designed and manufactured for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterised by the presence of infra-red radiation, flames or the projection of large amounts of molten material, including fire-fighters' equipment.	III
9.4 Equipment and/or accessories (whether or not detachable) designed and manufactured for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less	III
9.5 Equipment and/or accessories (whether or not detachable) designed and manufactured to provide only limited protection against chemical attack or ionising radiation.	III
9.6 Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against cleaning materials of weak action (for dishwashing, cleaning etc.), for professional use	I
9.7 Equipment and/or accessories (whether or not detachable) designed and manufactured to provide protection against mechanical action the effects of which are superficial (pricks due to sewing, gardening, dirty work, sports)	I
9.8 Equipment and/or accessories (whether or not detachable) designed and manufactured to protect against heat and risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50 °C or to dangerous impacts and against unexceptional cold weather, for professional use.	I
9.9 Dry gloves for divers.	II

10. PPE FOR PROTECTION AGAINST DROWNING OR FOR USE AS BUOYANCY AIDS

TYPE OF PPE	CATEGORY
10.1 All equipment designed and manufactured to prevent drowning or for use as buoyancy aids. Note: Equipment referred to in paragraph 1 of this Section includes also: - crampons, ropes and other equipment used to get out of water after falling through ice. - swimming suits with incorporated floats. - swimming armbands	II

11. PPE FOR PROTECTION AGAINST ELECTRICAL RISKS

TYPE OF PPE	CATEGORY
11.1 Note: Equipment for protection against electrical risks is already listed in above tables of this Annex. Dangerous voltages means a voltage equal to or exceeding 50 V alternating current or 75 V direct current.	III
11.2 Protective equipment (shoes, garments, etc.) against statistic electricity Note: this equipment is used in environments with potential risk of explosion.	II

12. PPE DESIGNED AND MANUFACTURED TO PROTECT AGAINST THE RESUT OF MECHANICAL ACTION

TYPE OF PPE	CATEGORY
12.1 All PPE designed and manufactured to protect the wearer against vibrations.	II
12.2 PPE designed and manufactured to protect the skin of the user against friction (e.g. patches).	I
12.3 PPE designed and manufactured to protect the wearer against increased risk levels arising from impacts with other persons or from falling while performing sports (e.g. backprotectors for mountainbikers, football shin-guards, ice hockey protectors, …)	II
12.4 PPE designed and manufactured to protect the wearer against impacts resulting from g-forces (e.g. karting collar, racing neck braces, …)	II
12.5 Equipment protecting against minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions (such as light anti-scalping helmets, gloves, light footwear, etc.)	I
12.6 Sports equipment protecting against minor impacts from falling (protection against bruises, abrasion, light burns, …), such as volleyball knee pads, ...	I

13. RESCUE EQUIPMENT

TYPE OF PPE	CATEGORY
13.1 Resuscitation masks: if the mask has, apart from allowing adequate artificial breathing, also a protective function for the rescuer (protection against contagion by contact with the mouth of the victim for instance) then they are PPE	Depending on the type of protection
13.2 If the rescue equipment is worn before the accident which prompts the rescue, then it is PPE Example: a wet suit worn continuously to prevent hypothermia in the event of falling into water is PPE	Depending on the type of protection

14. MOTORCYCLISTS' EQUIPMENT

TYPE OF PPE	CATEGORY
14.1 Motorcyclists' garments and additional protection (e.g. gloves, boots) only protecting against climatic conditions for professional use.	I
14.2 Motorcyclists' garments and additional protection (e.g. gloves, footwear) for which additional protection is provided (e.g. impact protectors for limb or back, pads for elbow or shoulders, protection against cuts and abrasion, …)	II

15. HIGH VISIBILITY CLOTHING AND ACCESSORIES

TYPE OF PPE	CATEGORY
15.1 High visibility clothing and accessories	II
15.2 High visibility accessories (e.g. free hanging accessories such as dangling tags)	II

When establishing the proper category for PPE, the level of risk it provides protection against evidently needs to be considered.

ANNEX 6

REQUIREMENTS TO BE MET BY A CONFORMITY ASSESSMENT BODY TO BE DESIGNATED FOR CONFORMITY ASSESSMENT

1. The assessment conformity body, its director, or members of the executing board of directors or the member of the managing board of that body, as well as the employees and other engaged persons (hereinafter: the staff) responsible for the implementation of conformity assessment in accordance with this Rulebook shall not be designers, manufacturers, suppliers, or installers of the PPE that is being inspected, or authorised representatives of any of those. They shall not be included, either directly or as authorised representatives, in designing, manufacturing, marketing, or maintenance of that equipment. This does not exclude the possibility of the exchange of technical information between the manufacturer and the conformity assessment body.
2. The body referred to in Section 1 of this Annex, as well as its staff, must implement the conformity assessment with the highest degree of professional integrity and technical competence, and must be free from any pressure or conflict of interest, particularly of financial nature, that might influence their judgement or the results of inspection, especially from the persons or a group of persons with an interest in the results of conformity assessment.
3. For every type of PPE for which it requests to be given notification, and for every conformity assessment process, the conformity assessment body shall, before and after the notification, have at its disposal the staff with technical knowledge, and adequate and suitable experience for performing the conformity assessment tasks.
4. The staff that is put in charge of performing the conformity assessment tasks shall also have:
   1) suitable working experience, and relevant authorisation for performing the conformity assessment tasks;
   2) the ability and independence in drawing up the reports and other documents of conformity, connected with the performed assessment and conducting the tests laid down by this Rulebook.
5. The conformity assessment body must have at its disposal necessary testing equipment, depending on the requirements contained in the Serbian standards from the List of Standard referred to in Article 14 of this Rulebook and the PPE type the conformity of which is being assessed, namely the basic requirements or the aspects of basic requirements with regard to which conformity assessment is conducted.
6. The impartiality of the staff carrying out the PPE conformity assessment must be guaranteed.
7. The remuneration, namely the award, for the staff shall not depend on the number of tests carried out or results of those tests.
8. a conformity assessment body must have a suitable general act laying down the procedure for the performance of conformity assessment tasks, including the procedure of deciding on the objections put forward with regard to the activities and decisions made by this body.
9. Conformity assessment body must have damage liability insurance.
10. The staff of the conformity assessment body shall be bound to observe professional secrecy with regard to all information obtained in carrying out the conformity assessment tasks, in accordance with tits general confidentiality act, this Rulebook, and other regulations.