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Based upon Article 20, paragraph 4 of the Law on product safety (Official Gazette of the Republic of Macedonia No. 33/2006), the Minister of Economy has adopted this

RULEBOOK ON PLACEMENT ON THE MARKET OF PERSONAL PROTECTIVE EQUIPMENT

I. GENERAL PROVISIONS

Article 1

This Rulebook prescribes the basic safety requirements for the personal protective equipment (hereinafter: equipment) in order to ensure the health protection and safety of users, certification procedures when marketed and the conditions needed to be met by the legal person involved in the certification procedure.

Article 2

For the purposes of this Rulebook, equipment shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

The equipment referred to in paragraph 1 of this Article shall also cover:

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;
2. a protective device or appliance combined, separable or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity;
3. interchangeable equipment components which are essential to its satisfactory functioning and used exclusively for such equipment.

For the purposes of this Rulebook, inspection shall mean examination of the equipment design, the equipment itself and examining its conformity with the certain requirements or, with general requirements, based upon an professional estimation.

Article 3

Any system placed on the market in conjunction with equipment 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.

Article 4

The provisions of this Rulebook shall not apply for:

1. equipment covered by another technical regulation designed to achieve the same objectives as this Rulebook with regard to placing on the market, free movement of goods and safety;
2. equipment designed and manufactured specifically for use by the armed forces or in the maintenance of law and order (helmets, shields, etc.);
3. equipment for self-defence (aerosol canisters, personal deterrent weapons, etc.);
4. equipment designed and manufactured for private use against:
   - adverse atmospheric conditions (headgear, seasonal clothing, footwear, umbrellas, etc.);
   - damp and water (dish-washing gloves, etc.);
   - heat (gloves etc.);
5. equipment intended for the protection or rescue of persons on vessels or aircraft, not worn all the time;
6. motorcycle and tricycle helmets and visors.

Article 5

The equipment covered by this Rulebook may be placed on the market and put into service only if, when properly maintained and used for their intended purpose, it does not endanger the health and safety of persons and, where appropriate, domestic animals or property.

The prescription of any requirements which are considered necessary to ensure user protection, provided that this does not give rise to modifications to equipment which could result in its non-conformity with the provisions of this Rulebook.

Article 6

equipment which are not in conformity with the provisions of this Rulebook may be shown at trade fairs, exhibitions, etc., 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 by the manufacturer or his representative established in the Republic of Macedonia.

Article 7

The equipment referred to in this Rulebook should satisfy the basic health and safety requirements laid down in Chapter II of this Rulebook.

II. BASIC HEALTH AND SAFETY REQUIREMENTS

1. General requirements applicable to all equipment

Article 8

Equipment must provide adequate protection against all risks encountered.

1.1. Design principles

1.1.1. Ergonomics

Article 9

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

1.1.2. Levels and classes of protection

1.1.2.1. Highest level of protection possible

Article 10

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 equipment would prevent its effective use during the period of exposure to the risk or normal performance of the activity.
1.1.2.2.Classes of protection appropriate to different levels of risk

Article 11

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

1.2. Innocuousness of equipment

1.2.1. Absence of risks and other 'inherent' nuisance factors

Article 12

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

1.2.1.1. Suitable constituent materials

Article 13

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

1.2.1.2.Satisfactory surface condition of all equipment parts in contact with the user

Article 14

Any equipment 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

Article 15

Any impediment caused by equipment to movements to be made, postures to be adopted and sensory perception must be minimized; nor must equipment cause movements which endanger the user or other persons.

1.3. Comfort and efficiency

1.3.1. Adaptation of equipment to user morphology

Article 16

Equipment 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.

In cases of paragraph 1 of this Article, it should be possible to optimize equipment adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

1.3.2. Weight and design strength

Article 17

Equipment must be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question in accordance with Articles 34 to 56 of this Rulebook, equipment 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 equipment designed for simultaneous use

Article 18

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

1.4. Information supplied by the manufacturer

Article 19

In addition to the name, surname and address or name and the headquarters of the manufacturer or his authorized representative established in the Republic of Macedonia, the notes that must be drawn up by the former and supplied when equipment is placed on the market must contain all relevant information on:

1. storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers should have no adverse effect on equipment or users when applied in accordance with the relevant instructions;

2. performance as recorded during technical tests to check the levels or classes of protection provided by the equipment in question;

3. suitable equipment accessories and the characteristics of appropriate spare parts;

4. the classes of protection appropriate to different levels of risk and the corresponding limits of use;

5. the obsolescence deadline or period of obsolescence of equipment or certain equipment components;

6. the type of packaging suitable for transport;

7. the significance of any markings in accordance with Article 31 of this Rulebook;

8. name, headquarters and the identification number of the legal person involved in the designing phase of the equipment.

The notes mentioned in paragraph 1 of this Article shall be precise and comprehensible and written in Macedonian language and in its Cyrillic alphabet.

2. Additional requirements common to several classes or types of equipment

3.

3.1.equipment incorporating adjustment systems

Article 20

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

3.2. Equipment 'enclosing' the parts of the body to be protected

Article 21

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

3.3. Equipment for the face, eyes and respiratory tract

Article 22

Any restriction of the user's field of vision or sight by equipment for the face, eyes or respiratory tract should be minimized.

The degree of optical neutrality of the vision systems of these equipment classes referred to in paragraph 1 of this Article should be compatible with the type of relatively meticulous and/or prolonged activities of the user.

If necessary, the equipment referred to in paragraph 1 of this Article should be treated or provided with facilities to prevent moisture formation.

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

3.4. Equipment subject to ageing

Article 23

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

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

Where appreciable and rapid deterioration in equipment performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter should, if possible, affix a mark to each item of equipment 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 should give this information in his notes.

3.5. Equipment which may be caught up during use

Article 24

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

3.6. Equipment for use in explosive atmospheres

Article 25

Equipment intended for use in explosive atmospheres should 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.

3.7. Equipment intended for emergency use or rapid installation and/or removal

Article 26

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

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

3.8. Equipment for use in very dangerous situations

Article 27

The information notes supplied by the manufacturer together with equipment for use in the very dangerous situations referred to in Article 82 point (a) of this Rulebook should include, in particular, data intended for the exclusive use of competent trained individuals who are qualified to interpret them and ensure their application by the user.

The information notes referred to in paragraph 1 of this Article should also describe the procedure to be adopted in order to verify that equipment is correctly adjusted and functional when worn by the user.

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

3.9. Equipment incorporating components which can be adjusted or removed by the user

Article 28

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

3.10. Equipment for connection to another, external complementary device

Article 29

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

3.11. Equipment incorporating a fluid circulation system

Article 30

If equipment incorporates a fluid circulation system, the latter should 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.

3.12. Equipment bearing one or more identification or recognition marks directly or indirectly relating to health and safety

Article 31

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

The marks mentioned in paragraph 1 of this Article should be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks

incorporate words or sentences, they should appear in the Macedonian language and in its Cyrillic alphabet.

If equipment (or a equipment component) is too small to allow all or part of the necessary marking to be affixed, the relevant information should be mentioned on the packing and in the manufacturer's notes.

3.13. Equipment in the form of clothing capable of signalling the user's presence visually

Article 32

equipment 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.

3.14. Multi-risk equipment

Article 33

All equipment 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 the Articles 34 to 56 of this Rulebook.

4. Additional requirements specific to particular risks

4.1. Protection against mechanical impact

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

Article 34

Suitable equipment for this type of risk should 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 equipment for the foreseeable period of wear.

4.1.2. Falls

4.1.2.1. Prevention of falls due to slipping

Article 35

The outsoles for footwear designed to prevent slipping should 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.

4.1.2.2.Prevention of falls from a height

Article 36

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

The equipment referred to in paragraph 1 of this Article should 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 equipment component which might cause the user to fall can be expected to occur.

The equipment referred to in paragraph 1 of this Article should also ensure that after breaking 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:

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

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

4.1.3. Mechanical vibration

Article 37

Equipment designed to prevent the effects of mechanical vibrations should 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.

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

Article 38

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

4.3.Protection against physical injury (abrasion, perforation, cuts, bites)

Article 39

Equipment 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 equipment classes provide sufficient resistance to abrasion, perforation and gashing in accordance with Articles 34 to 37 of this Rulebook under the foreseeable conditions of use.

4.4. Prevention of drowning (lifejackets, armbands and lifesaving suits)

Article 40

Equipment designed to prevent drowning should 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.

Equipment 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:

1. equipment should, 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;
2. inflatable equipment should be capable of inflating rapidly and fully.

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

- it should have all the inflation devices referred to in the second paragraph of this Article, and/or a light or sound-signalling device;
- it should have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- it should be suitable for prolonged use throughout the period of activity exposing the user, who is possibly dressed, to the risk of falling into the liquid medium or requiring his immersion into it.

4.4.1. Buoyancy aids

Article 41

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 equipment mentioned in paragraph 1 of this Rulebook should 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.

4.5. Protection against the harmful effects of noise

Article 42

Equipment designed to prevent the harmful effects of noise should 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 by Regulations on the protection of workers from the risks related to exposure to noise at work.

The equipment mentioned in paragraph 1 of this Article should bear a label indicating the noise attenuation level and the value of the comfort index provided by the equipment; should this not be possible, the label should be fixed to the packaging.

4.6. Protection against heat and/or fire

Article 43

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

4.6.1. Equipment constituent materials and other components

Article 44

Constituent materials and other components suitable for protection against radiant and convective heat should 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 these materials and components should be reflective, its reflective power must be appropriate to the intensity of the heat flux due to radiation in the infra-red range.

Materials and other components of equipment intended for brief use in high-temperature environments and of equipment which may be splashed by hot products such as large quantities of molten material should also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed his equipment.

equipment materials and other components which may be splashed by large amounts of hot products should also possess sufficient mechanical-impact absorbency in accordance with the Articles 34 to 37 of this Rulebook.

equipment materials and other components which may accidentally come into contact with flame and those used in the manufacture of fire-fighting equipment should 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.

4.6.2. Complete equipment ready for use

Article 45

Under the foreseeable conditions of use:

1. the quantity of heat transmitted by equipment to the user should 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. equipment should if necessary prevent liquid or steam penetration and should not cause burns resulting from contact between its protective integument and the user.

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

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

The manufacturer's notes accompanying each equipment model intended for brief use in high-temperature environments should 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.

4.7.Protection against cold

Article 46

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

4.7.1. equipment constituent materials and other components

Article 47

Constituent materials and other components suitable for protection against cold should 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 equipment intended for use in a low-temperature environment should retain the degree of flexibility required for the necessary gestures and postures.

equipment materials and other components which may be splashed by large amounts of cold products should also possess sufficient mechanical-impact absorbency in accordance with the Articles 34 to 37 of this Rulebook.

4.7.2. Complete equipment ready for use

Article 48

Under the foreseeable conditions of use:

1. the flux transmitted by equipment to the user should 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. equipment must as far as possible prevent the penetration of such liquids as rain water and should not cause injuries resulting from contact between its cold protective integument and the user.

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

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

4.8.Protection against electric shock

Article 49

Equipment designed to protect all or part of the body against the effects of electric current should 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 equipment classes should 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, equipment types intended exclusively for use during work or activities in electrical installations which are or may be under tension should bear markings indicating, in particular, their protection class and (or) corresponding operating voltage, their serial number and their date of manufacture;

Space should also be provided, outside the protective integument of such equipment mentioned in paragraph 3 of this Article, 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 should indicate, in particular, the exclusive use for which these equipment types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

4.9. Radiation protection

4.9.1. Non-ionizing radiation

Article 50

Equipment designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation should 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 this end, protective glasses referred to in paragraph 1 of this Article should 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.

The protective glasses mentioned in paragraph 2 of this Article should not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens 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 should be classified in the ascending order of their protection factors and the manufacturer's notes should indicate, in particular, the transmission curves which make it possible to select the most appropriate equipment 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 should be marked on all specimens of filtering glasses by the manufacturer.

4.9.2. Ionizing radiation

4.9.2.1.Protection against external radioactive contamination

Article 51

Equipment constituent materials and other components designed to protect all or part of the body against radioactive dust, gases, liquids or mixtures thereof should 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 equipment is subject should not prejudice its possible re-use during the foreseeable useful life of these classes of equipment.

4.9.2.2. Limited protection against external irradiation

Article 52

Equipment intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, should 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 equipment classes referred to in paragraph 1 of this Rulebook should 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 the Article 17 of this Rulebook.

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

4.10. Protection against dangerous substances and infective agents

4.10.1. Respiratory protection

Article 53

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

The breathable air supplied to the user by the equipment should 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 these equipment classes referred to in paragraph 1 of this Article should 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 face piece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity should 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 equipment should 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 equipment correctly.

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

4.10.2. Protection against cutaneous and ocular contact

Article 54

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

To this end, the constituent materials and other components of these equipment classes referred to in paragraph 1 of this Rulebook should 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 equipment in question, the latter should be subjected to standard tests with a view to their classification on the basis of efficiency.

equipment which is considered to be in conformity with the test specifications should 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 should also contain 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 wear under the different foreseeable conditions of use.

4.11. Safety devices for diving equipment

4.11.1. Breathing equipment

Article 55

The breathing equipment should 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.

Article 56

Where the foreseeable conditions of use so require, the equipment should comprise:

1. a suit which protects the user against the pressure resulting from the depth of immersion in accordance with the Article 38 of this Rulebook and/or against cold in accordance with the Article 46 of this Rulebook;
2. an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture in accordance with the Article 27 of this Rulebook;
3. a life-saving suit enabling the user to return to the surface in accordance with the Article 41 of this Rulebook.

III. CONFORMITY ASSESSMENT

1. Presumption of conformity

Article 57

Equipment and its components bearing the CE marking and accompanied with the EC declaration of conformity shall be regarded as complying with the provisions of this Rulebook, including the certification procedures.

Equipment and its components which comply with the national standards developed on the basis of European harmonized standards (hereinafter: national standards) shall be regarded as harmonized with the essential requirements given in Chapter II of this Rulebook.

Article 58

In cases where the equipment are subject to other technical regulations with regards to special requirements and which prescribe for placement of conformity marking, the conformity marking shall proof the compliance with the provisions of those technical regulations.

2. Certification procedures

Article 59

Before placing a equipment model on the market, the manufacturer or his authorized representative established in the Republic of Macedonia shall assemble the technical documentation, referred to in Articles 67 and 68 of this Rulebook so that this can, if necessary, be submitted to the competent state authorities.

Article 60

Prior to the series production of equipment other than those referred to in Article 61 of this Rulebook, the manufacturer or his authorized representative established in the Republic of Macedonia shall submit a model for EC type-examination as referred to in Chapter V of this Rulebook.

Article 61

Type-examination shall not be required in the case of equipment models of simple design where the designer 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 referred to in paragraph 1 of this Article shall cover exclusively equipment intended to protect the wearer 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 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 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).

Article 62

Production of equipment shall be subject:

a) according to the manufacturer's choice, to one of the two procedures referred to in Chapter VI of this Rulebook in the case of equipment 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.
The category referred to in point (a) of this Article shall cover exclusively:

- filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases;
- respiratory protection devices providing full insulation from the atmosphere, including those for use in diving;
- equipment providing only limited protection against chemical attack or against ionizing radiation;
- 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;
- 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;
- equipment to protect against falls from a height;
- equipment against electrical risks and dangerous voltages or that used as insulation in high-voltage work;

(b) the declaration of conformity referred to in Article 69 of this Rulebook for all types of equipment.

3. Legal persons which perform the certification

Article 63

The legal persons which are authorized to execute the certification procedure for equipment (hereinafter: authorized body) shall meet the criteria for performing the certification, listed in Chapter IV of this Rulebook.

Article 64

The authorized body which shall meet the criteria for performing the certification, listed in Chapter IV of this Rulebook may be authorized for one or two certification procedures of equipment:

- type examination in accordance with the provisions from Chapter V of this Rulebook,

- control of the final product in accordance with the provisions from Chapter VI of this Rulebook.

The authorized body referred to in paragraph 1 of this Article should be granted with a unique identification number of the body.

Article 65

The authorised body which performs the certification procedures of the equipment shall constantly fulfil the criteria given in Chapter IV of this Rulebook and shall be able to perform the specific tasks from the national standards.

Article 66

The designation (notification) procedure of the notified body in the European Commission shall be executed in accordance with product safety regulations.

4. Technical documentation supplied by the manufacturer

Article 67

The documentation referred to in Article 59 of this Article should comprise all relevant data on the means used by the manufacturer to ensure that a equipment complies with the basic requirements relating to it.

Article 68

In the case of equipment models referred to in Article 60 of this Rulebook the documentation must comprise in particular:
1.the manufacturer's technical file consisting of:
(a) overall and detailed plans of the equipment 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;
(b) an exhaustive list of the basic safety requirements and of the national standards or other technical specifications, referred to in Chapter II of this Rulebook, 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 equipment with the harmonized standards or other technical specifications and to maintain the quality level;
3.a copy of the information notice referred to in the Article 19 of this Rulebook.

5. Declaration of production conformity

Article 69

Declaration of conformity is a procedure whereby the manufacturer or its authorized representative established in the Republic of Macedonia:
1. draws up a declaration using the form laid down in Appendix I enclosed to this Rulebook, certifying that the equipment placed on the market are in conformity with the provisions of this Rulebook with a view to its submission to the competent authorities;

2. affixes the mark of conformity provided for by Chapter VII of this Rulebook to each equipment.

IV. CONDITIONS TO BE FULFILLED BY THE AUTHORISED BODIES WHO PARTICIPATE IN THE CERTIIFCATION PROCEDURES

Article 70

The authorized body, its responsible personnel (director, manager, head etc.), its technical and expert personnel responsible for carrying out the assessment, development of reports, issuing of certificate and execution of inspections may not be the designer, manufacturer, supplier of the equipment, nor the authorized representative of any of those parties.

The authorized body, their responsible personnel (director, manager, head etc.) and expert and technical personnel should not become directly nor indirectly involved in the design, construction, marketing or maintenance of the equipment, nor represent the parties engaged in these activities. This does not preclude the possibility of exchanges of technical information between the manufacturer of equipment and those bodies.

Article 71

The authorized body and its expert and technical personnel should carry out the inspections with the highest degree of professional integrity and technical competence and should be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of the inspection, especially from persons or groups of persons with an interest in the results of inspections.

Article 72

The authorized body should have at its disposal the necessary expert personnel to enable it to perform properly the technical and administrative tasks connected with the inspection operations.

The authorized body shall have at least three expert full time employees who will be involved in the certification process, as follows:

- a engineer in protection at work with a continuous experience of minimum five years in operations related to examination of equipment,
- an engineer in the field which is examined with a continuous experience of five years in his field of expertise,
- a mechanical technical executor with at least high school degree and at least three years of continuous experience in his field of expertise.

Article 73

The expert personnel responsible for inspections should have:

- sound technical and professional training and qualification in accordance with the national standards,
- satisfactory knowledge of the requirements of the inspections they carry out and adequate experience of such operations,

- the ability required to draw up the certificates, records and reports to demonstrate that the inspections have been carried out.

Article 74

The authorized body should ensure the impartiality of its expert personnel when performing the inspections and their remuneration should not depend on number of performed inspections nor on the results from such inspections.

The authorized body should have adequate liability insurance.

The authorized body, its responsible persons and expert personnel should respect the professional secrecy with regard to all information gained in carrying out their tasks (except vis-à-vis the competent national authorities) under this Rulebook or any provision of national law related to the certification procedures for equipment.

V. TYPE EXAMINATION

Article 75

For the purposes of this Rulebook, type-examination is the procedure whereby the authorized body establishes and certifies that the equipment model in question satisfies the relevant provisions of this Rulebook.

Article 76

The application for type-examination for the design in question shall be lodged by the manufacturer or by his authorized representative established within the Republic of Macedonia with a single authorised body of his choice.

The application referred to in paragraph 1 of this Rulebook should include:

- name, surname and address or name and the headquarters of the manufacturer or his authorized representative established in the Republic of Macedonia and of the plant where the concerned equipment is manufactured,
- the manufacturer's technical file referred to in Articles 67 and 68 of this Rulebook.

The applicant referred to in paragraph 1 shall submit appropriate number of specimens of the model to be approved along with the application.

Article 77

The authorized body shall conduct the type-examination in accordance with the following procedures:

1. Examination of the manufacturer's technical file:

- It shall examine the manufacturer's technical file to establish its suitability with respect to the national standards;
- where a manufacturer has not applied, or has only partly applied, the national standards or where there are no such standards, the body of which notification has been given should check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements before examining the manufacturer's technical file to establish its suitability with respect to these technical specifications.

2. Examination of the model:

- when examining the model, the authorised body shall verify that it has been produced in accordance with the manufacturer's technical file and can be used in complete safety for its intended purpose;
- it shall conduct the necessary examinations and tests to establish the conformity of the model with the national standards;
- where a manufacturer has not applied or has only partly applied the national standards or where there are no such standards the body of which notification has been given shall conduct the necessary examinations and tests to establish the conformity of the model with the technical specifications used by the manufacturer, subject to their being suitable with respect to these basic requirements.

Article 78

If the model satisfies the relevant provisions, the authorised body shall draw up a type-examination certificate and shall notify the applicant to this effect.

The certificate referred to in paragraph 1 of this Article shall reproduce the findings of the examination, indicate any conditions attaching to its issue and incorporate the descriptions and drawings necessary for the identification of the approved model.

The other approved bodies may obtain a copy of the certificate referred to in paragraph 1 of this Article and, in response to a reasoned request, a copy of the manufacturer's technical file and the reports of the examinations and tests conducted.

The file referred to in paragraph 1 of this Article shall be held at the disposal of the competent authorities for 10 years following the placing of the equipment on the market.

Article 79

Any authorised body which refuses to issue a type-examination certificate shall inform the other approved inspection bodies of this fact.

An authorised body withdrawing an type-examination certificate shall inform the national authorities, to this effect.

VI. CHECKING OF MANUFACTURED equipment

1.Quality control system for the final product

Article 80

A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of equipment and tests, ensures the homogeneity of production and the conformity of equipment with the type described in the type-approval certificate and with the relevant basic requirements set out in the provisions of this Rulebook.

Article 81

An authorised body chosen by a manufacturer, shall carry out the necessary checks.

The checks referred to in paragraph 1 of this Article checks shall be carried out at random, normally at intervals of at least one year.

Article 82

An adequate sample of equipment taken by the body of which notification has been given shall be examined and appropriate tests defined in the national standards or necessary to show conformity to the basic requirements of this Rulebook shall be carried out to check the conformity of equipment.

Article 83

Where a body is not the body that issued the relevant type-approval certificate it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the conformity of samples.

Article 84

The body of which notification has been given shall provide the manufacturer with a test report. If the report concludes that production is not homogeneous or that the equipment examined do not conform to the type described in the type-approval certificate or the relevant basic requirements, the body shall take measures appropriate to the nature of the fault or faults recorded and inform the relevant national authority.

Article 85

The manufacturer should be able to present, on request, the report of the body of which notification has been given.

2. System for ensuring quality of production by means of monitoring

2.1. The system

Article 86

Under the system for ensuring quality of production by means of monitoring the manufacturer submits an application for the approval of his quality-control system to an authorised body of his choice.

The application referred to in paragraph 1 of this Rulebook should include:

1. all the information relating to the category of equipment concerned, including, where appropriate, documentation relating to the model approved,
2. documentation on the quality-control system,
3. the undertaking to maintain the obligations arising from the quality-control system and to maintain its adequacy and efficiency.

Article 87

Under the quality-control system, each equipment shall be examined and the appropriate tests referred to in Article 82 of this Rulebook shall be carried out to check their conformity to the relevant basic requirements of this Rulebook.

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

1. the quality objectives, the organization chart, the responsibilities of executives and their powers in respect of product quality;
2. the checks and tests which should be carried out after manufacture;
3. the means to be employed to check the efficient operation of the quality-control system.

Article 88

The authorized body shall assess the quality-control system to determine whether it satisfies the provisions referred to in Article 87 of this Rulebook. The authorized body shall assume that quality-control systems applying the relevant national standard are harmonized with the provisions of Article 87 of this Rulebook.

The authorized body carrying out audits shall make all necessary objective evaluations of the components of the quality-control system and shall check in particular whether the system ensures conformity of equipment manufactured with the approved model.

The decision shall be communicated to the manufacturer. It shall include the conclusions of the check and the reasoned assessment decision.

Article 89

The manufacturer shall inform the body which approved the quality-control system of any plan to alter the quality-control system.

The authorized body shall examine the proposed changes and decide whether the altered quality-control system satisfies the relevant provisions of this Rulebook.

The authorized body shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.

2.2.Supervision

Article 90

The purpose of supervision is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality-control system.

Article 91

The manufacturer shall authorize the body to have access, for purposes of inspection, to equipment inspection, testing and storage sites and shall provide the body with all requisite information, in particular:

1. the documentation concerning the quality-control system,
2. technical documentation,
3. quality control manuals.

Article 92

The authorized 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.

Article 93

In addition the authorized body may pay unexpected visits to the manufacturer. In the course of such visits the authorized body shall provide the manufacturer with a report of the visit and, if appropriate, with an audit report.

Article 94

The manufacturer should be able to present, on request, the report of the body of which notification has been given.

VII. 'CE' CONFORMITY MARKING

Article 95

CE-marking should contain the initials "CE". 'CE' conformity marking consist of the initials CE taking the form given in Appendix 2 enclosed to this Rulebook.

Should the 'CE'-marking be reduced or enlarged the proportions given in the Appendix 2 must be complied with.

Various components of the 'CE'-marking shall, in essence, have the same vertical dimensions, which may not be less than 5 mm and those minimal dimensions may be different only for a equipment with small dimensions.

The CE marking shall be accompanied by the identification number of the notified body involved at the production control phase in accordance with Articles 80 to 94 of this Rulebook.

Article 96

The CE mark shall be affixed to each production equipment and its packaging so as to be visible, legible and indelible throughout the foreseeable useful life of that equipment.

Provided the CE mark can not be affixed on the equipment due to its characteristics, the mark shall be placed on the equipment packaging.

Article 97

Equipment shall not bear markings which may mislead natural and legal persons with regards to the meaning and the form of the 'CE'-marking.

Any other marking may be affixed either to equipment or to its packaging provided that the visibility and legibility of the CE marking is not thereby reduced.

VIII. TRANSITIONAL AND FINAL PROVISIONS

Article 98

The provisions from this Rulebook, which refer to 'CE'-marking, shall apply after the accession of the Republic of Macedonia in the European Union or after the entry into force of an appropriate Protocol with the European Community on conformity assessment and after

the designation (notification) of and notified body of Republic of Macedonia in the European Commission.

Article 99

Before the period of the accession of the Republic of Macedonia in the European Union, the manufacturer may permit the placement on the market of equipment without conformity or CE marking, providing it is produced in the Republic of Macedonia and complies with the essential requirements as laid down in the provisions of this Rulebook.

In cases of paragraph 1 of this Article, the equipment manufacturer should provide an equipment conformity certificate from the authorized body for conformity assessment in the Republic of Macedonia, in accordance with the certification procedures, and taking into account the appropriate national standards.

The certificate of conformity issued in accordance with paragraph 2 of this Article, shall replace the conformity mark and it shall be kept for a period of 10 years after the last of the equipment has been verified. Documentation for every item of equipment shall be accompanied by a copy of the conformity certificate, verified by the manufacturer.

Article 100

Before the period of the accession of the Republic of Macedonia in the European Union or before entrance into force of an appropriate Protocol for conformity assessment with the European Community or before entrance into force of an appropriate bilateral agreement for mutual document recognition, any equipment imported and placed on the market within the Republic of Macedonia shall possess a conformity certificate issued by an authorized body established in the Republic of Macedonia in accordance with the provisions of this Rulebook. The authorized body may issue a conformity certificate solely for the appropriate procedure which the body is authorized for.

The certificate of conformity referred to in paragraph 1 of this Article shall be issued based upon EC declaration of conformity from the manufacturer, EC type-examination certificate, certificate of approved quality-control system, results from the conducted tests and after an analysis on the level of conformity with the essential requirements as set out in the provisions from this Rulebook.

The certificate of conformity referred to in paragraph 1 of this Article shall be issued for every type of equipment and it shall accompany its documentation.

Where non-conformity of the equipment with the requirements set out in the provisions of this Rulebook is established, a conformity certificate shall not be issued. In accordance with the law, the authorized body shall forthwith inform the Commission for product safety thereof.

Article 101

After the accession of the Republic of Macedonia in the European Union or after the entry into force of an appropriate Protocol with the European Community on conformity assessment, for the purposes of this Rulebook, the following terms shall apply:

- "authorized representative established in the European Union or in the Republic of Macedonia" instead of "authorized representative established in the Republic of Macedonia";
- "EC declaration of conformity" instead of "Declaration of conformity";
- “EC type-examination” instead of “type-examination”;

- “EC type-examination certificate” instead of “type-examination certificate”;
- "CE-marking" instead of "Conformity marking";

The provisions from this Rulebook which refer to CE-marking, and after the designation (notification) of a body from Republic of Macedonia in the European Commission, for the purposes of this Rulebook, the following terms shall apply:

- "CE-marking" instead of "Conformity marking";
- “notified body” instead of “authorized body”;
- “identification number of the notified body” instead of “identification number of the authorized body”. Identification number of the notified body is the number granted by the European Commission.

Article 102

The provisions of the Rulebook on personal protection at work and personal protective equipment (Official Gazette of SFRYugoslavia No 35/69) shall cease to be valid. 35/69).

Article 103

This Rulebook shall enter into force on the 8th day following its publication in the “Official Gazette of the Republic of Macedonia”.

MINISTER

Vera Rafajlovska, signed

Appendix 1

DECLARATION OF CONFORMITY

The manufacturer or his authorized representative established in the Republic of Macedonia[1]

_____
_____
_____

declares that the new equipment described hereafter[2]

_____
_____
_____
_____
_____

is in conformity with the provisions of Rulebook on placement on the market of equipment (Official Gazette of the Republic of Macedonia N° …….) and, where such is the case, with the national standard N° ……. (for the equipment referred to in Article 61 from the Rulebook on placement on the market of the equipment)
is identical to the equipment which is the subject of certificate of conformity N° ..... issued by ([3]) ([4])

_____
_____

is subject to the procedure set out in Articles 80 to 85 or in Articles 86 to 94 ([4]) of the Rulebook on placement on the market of personal protective equipment (PPE) (Official Gazette of the Republic of Macedonia No …….) under the supervision of the authorized body ([3]) ……

_____
_____
_____

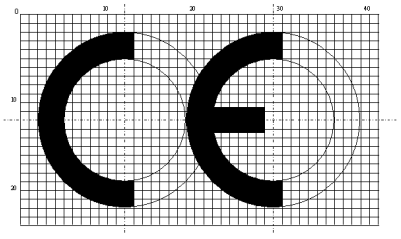
In ……., on ……. Signature ([5]) _____

([1]) Business name and full address, authorized representative should give the business name and address of the manufacturer.
([2]) Description of the personal protective equipment (make, type, serial number, etc.).
([3]) Name and address of the authorized body
([4]) Delete whichever is inapplicable.
([5]) Name and position of the person empowered to sign on behalf of the manufacturer or his authorized representative.

Appendix 2

“CE” MARKING OF CONFORMITY AND INFORMATION

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



ОБРАЗЕЦ Бр. 1 Поимник на термини и изрази

За секој CELEX-број на правниот акт на ЕУ се пополнува овој Образец бр.1 - Поимник на термини и изрази. Пополнетиот Образец бр.1 прикачете го на крајот на преводот, така што преводот и Образецот бр.1 ќе претставуваат ЕДЕН документ.

CELEX-број	/
Наслов на документот (АНГ)	RULEBOOK ON PLACEMENT ON THE MARKET OF PERSONAL PROTECTIVE EQUIPMENT
Наслов на документот (МАК)	ПРАВИЛНИК ЗА ПУШТАЊЕ НА ПАЗАР НА ЛИЧНА ЗАШТИТНА ОПРЕМА

Област на примена	

Агенција за преведување	Еуролингва		**Преведувач**		
Тел.	070/305760	**е-пошта**	eurolingua@eurolingua.com.mk	**Датум**	26.03.2007

Место на зборот во текстот (член, став, точка, прилог ...)	Изворен збор (АНГ)	Превод (МАК)	Забелешка / Коментар	Извор на преводот[6] (користен речник / МАКТЕРМ)
	EC (CE) marking	ЕС (СЕ) ознака		МАКТЕРМ
	EC (CE) type approval	ЕС (СЕ) одобрение на тип		МАКТЕРМ
	EC certificate of conformity	ЕС потврда за сообразност		МАКТЕРМ
	EC declaration	ЕС декларација		МАКТЕРМ
	EC declaration of conformity to type	ЕС декларација за усогласеност со тип		МАКТЕРМ
	EC declaration of production conformity	ЕС декларација за сообразност на производството		МАКТЕРМ
	EC design examination certificate	сертификат за ЕС-испитување на дизајн		МАКТЕРМ
	protective integument	заштитна обвивка		МАКТЕРМ
	personal protective equipment (PPE)	опрема за лична заштита		

[6] КОРИСТЕН РЕЧНИК/ МАКТЕРМ – Ве молиме, запишете го името на речникот што е користен при преводот. Доколку терминот се наоѓа во МАКТЕРМ - базата на термини на веб-страницата на СЕП, Ве молиме нотирајте. Слободен пристап до базата на термини имаат сите корисници во процесот.