



EUROPEAN
COMMISSION

Brussels, 27.3.2014
COM(2014) 186 final

ANNEXES 1 to 11

ANNEXES

to the

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on personal protective equipment

{SWD(2014) 118 final}

{SWD(2014) 119 final}

ANNEX I

Risk Categories of PPE

Category I

PPE intended to protect users against minimal risks. Category I includes exclusively PPE intended to protect users against the following risks:

- (a) superficial mechanical injury;
- (b) contact with water or cleaning materials of weak action;
- (c) contact with hot surfaces not exceeding 50°C;
- (d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- (e) atmospheric conditions that are not of an extreme nature.

Category II

Category II includes:

- (a) PPE intended to protect users against risks other than those listed in Categories I and III;
- (b) made-to-measure PPE except where such PPE is intended to protect users against risks listed in Category I.

Category III

PPE intended to protect users against very serious risks. Category III includes exclusively PPE intended to protect users against the following risks:

- (a) inhalation of harmful substances;
- (b) aggressive chemicals;
- (c) ionising radiation;
- (d) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100°C;
- (e) low-temperature environments the effects of which are comparable to those of an air temperature of -50°C or less;
- (f) falling from a height;
- (g) electric shock and live working;
- (h) drowning;
- (i) cuts by hand-held chain-saws;
- (j) high-pressure cutting;
- (k) bullet wounds or knife stabs;
- (l) harmful noise.

ANNEX II

Essential health and safety requirements

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against the risks against which it is intended to protect.

1.1. Design principles

1.1.1. Ergonomics

PPE must be designed and manufactured so 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 level possible.

1.1.2. Levels and classes of protection

1.1.2.1. Optimum level of protection

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 exposure to the risk or the normal performance of the activity.

1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable 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 inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

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

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

1.2.1.3. Maximum permissible user impediment

PPE shall hinder as little as possible the actions to be carried out, the postures to be adopted and sensory perceptions; furthermore, use of the PPE must not engender actions which might endanger the user or other persons.

1.3. Comfort and effectiveness

1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness.

As well as the specific additional requirements which they must satisfy in order to provide adequate protection against the risks for which they are intended, PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of types of PPE intended for simultaneous use

If the same manufacturer places on the market several models of PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.4. Manufacturer's instructions

In addition to the name and address of the manufacturer or his authorized representative, or both, the instructions that must be drawn up by the manufacturer and supplied with the PPE when it is placed on the market must contain all relevant information on:

- (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user 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;
- (c) accessories that may be used with the PPE 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 date or period of obsolescence of the PPE or of certain of its components;
- (f) the type of packaging suitable for transport;
- (g) the significance of any markings (see 2.12);
- (h) where applicable, the references of other Union harmonisation legislation;
- (i) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE.

These instructions, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in 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; otherwise, it must be equipped with means of absorbing perspiration.

2.3. PPE for the face, eyes and respiratory system

PPE for the face, eyes or respiratory system shall restrict the user's field of vision and sight as little as possible.

The screens for these types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, they must be treated or provided with means to prevent misting up.

Models of PPE 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 performance of new PPE may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly and unambiguously marked on each item of PPE or each interchangeable component for PPE placed on the market and on their packaging.

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

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking 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 instructions.

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 potentially explosive atmospheres

PPE intended for use in potentially 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 rapid intervention or to be put on or removed rapidly

These types of PPE must be designed and manufactured to minimize the time required for putting on and removing the equipment.

Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate them quickly and easily.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

They must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where the PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, this must be designed and placed so that it can be perceived by the user in the foreseeable conditions of use.

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

Where PPE incorporates components which can be adjusted or removed by the user for replacement purposes, they must be designed and manufactured so that they can be easily attached and removed without tools.

2.10. PPE for connection to complementary equipment external to the PPE

Where PPE incorporates a connexion system permitting its connection to other, complementary equipment, the means of attachment must be designed and manufactured to enable it to be mounted only on appropriate equipment.

2.11. PPE incorporating a fluid circulation system

Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.

2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

The identification markings or indicators directly or indirectly relating to health and safety affixed to these types of PPE must, if possible, take the form of harmonized pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, these markings must be complete, precise and

comprehensible so as to prevent any misinterpretation; in particular, when such markings include words or sentences, the latter must be written in the official language(s) of the Member State where the equipment is to be used.

Where the PPE (or the interchangeable component for PPE) 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 instructions.

2.13. PPE capable of signalling the user's presence visually

PPE 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 or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

2.14. Multi-risk PPE

PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured to satisfy, in particular, the essential health and safety requirements specific to each of those risks.

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. Protection against mechanical impact

3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle

PPE intended 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 means of shock-absorption 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 of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means to ensure adequate grip by friction, studs or spikes, having regard to the nature or state of the ground surface.

3.1.2.2. Prevention of falls from a height

PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimized to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.

It 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 instructions must specify, in particular, all relevant information relating to:

- (a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;
- (b) the proper way of putting on the body harness and of attaching the connexion system to the reliable anchorage point.

3.1.3. Mechanical vibration

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.

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 mechanical injuries

PPE constituent materials and other components designed to protect all or part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also 3. 1) under the foreseeable conditions of use.

3.4. Protection in the water

3.4.1. Prevention of drowning

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 by gas which can be manually or automatically released, or orally.

Under the foreseeable conditions of use:

- (a) 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;
- (b) 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:

- (a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound-signalling device;
- (b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- (c) they 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.

3.4.2. *Buoyancy aids*

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, this PPE 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 to rescue other persons.

3.5. Protection against the harmful effects of noise

PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not under any circumstances exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council¹.

Each item of PPE must bear labelling indicating the noise attenuation level 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 the foreseeable conditions of use.

3.6.1. PPE constituent materials and other components

Constituent materials and other components intended 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 these materials and components 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 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 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 (see 3.1).

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:

- (a) 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;
- (b) the PPE must if necessary prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

¹ Directive 2003/10/EC of the European Parliament and of the Council of 6 February 2003 on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (OJ L 42, 15.2.2003, p. 38).

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 instructions accompanying PPE 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 intended.

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 (see 3.1).

3.7.2. Complete PPE ready for use

Under the foreseeable conditions of use the following requirements apply:

- (a) 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;
- (b) 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 instructions accompanying PPE 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

3.8.1. Insulating equipment

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 types of PPE 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 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 instructions must indicate, in particular, the exclusive use for which these PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

3.8.2. Conductive equipment

Conductive PPE intended for live working at high voltages shall be designed and manufactured to ensure that there is no difference of potential between the user and the installations on which he is intervening.

3.9. Radiation protection

3.9.1. Non-ionizing 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 this end, protective glasses must be so designed and manufactured as to possess, for each harmful wave length, 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.

Furthermore, 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 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 must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use

such as the distance from the 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. Ionizing 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 types of equipment.

3.9.2.2. Protection against external irradiation

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 types of PPE 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 (see 1.3.2).

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

3.10. Protection against dangerous substances and infectious agents

3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an 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 equipment or by supply from an external unpolluted source.

The constituent materials and other components of these types of PPE must be chosen or designed and incorporated 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 keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear the manufacturer's identification mark and details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also, indicate the time limit for the storage of new filters 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 permeation of such substances and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of these types of PPE must be chosen or designed and incorporated 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 infectious agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking 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 instructions 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 wear under the different foreseeable conditions of use.

3.11. Diving 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.

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

- (a) a suit which protects the user against cold (see 3.7);
- (b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see 2.8);
- (c) a life-saving device enabling the user to return to the surface.

ANNEX III

Technical documentation for PPE

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

The technical documentation shall include at least the following elements:

1. a complete description of the PPE and of its intended use;
2. an assessment of the risk(s) against which the PPE is intended to protect;
3. a list of the essential health and safety requirements that are applicable to the PPE;
4. design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies, and circuits;
5. the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point 4 and of the operation of the PPE;
6. the reference(s) of the harmonised standard(s) referred to in Article 14 that have been applied for the design and manufacture of the PPE; in the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
7. where harmonised standards have not been applied or only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
8. the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
9. reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
10. a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
11. a copy of the manufacturer's instructions referred to in point 1.4 of Annex II;
12. for made-to-measure PPE, all the necessary instructions of the designer of the basic model for manufacturing made-to-measure PPE on the basis of the approved basic model.

ANNEX IV

Internal production control

(Module A)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the PPE concerned satisfies the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.
2. Technical documentation

The manufacturer shall establish the technical documentation described in Annex III. The documentation shall make it possible to assess the conformity of the PPE to the applicable requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE.
3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE with the technical documentation referred to in point 2 and with the applicable essential health and safety requirements.
4. CE marking and EU declaration of conformity
 - 4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable essential health and safety requirements.
 - 4.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.

A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.
5. Authorised representative

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

ANNEX V

EU type-examination

(Module B)

1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

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

3. Application for EU type-examination

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

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the technical documentation described in Annex III. The documentation shall make it possible to assess the conformity of the PPE to the applicable requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the PPE;
- (d) the specimen(s) of the PPE representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. For individually adapted PPE, specimens shall be provided that are representative of the range of different users;
- (e) for individually adapted PPE, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

4. EU type-examination

The notified body shall:

- (a) examine the technical documentation to assess the adequacy of the technical design of the PPE;
- (b) for individually adapted PPE, examine the description of the measures referred to in point 3 to assess their adequacy;
- (c) for made-to-measure PPE, examine the instructions of the designer of the basic model for manufacturing made-to-measure PPE on the basis of the approved basic model to assess their adequacy;
- (d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed

in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed in accordance with other technical specifications;

- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
- (f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.

5. Evaluation report

The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. EU type-examination certificate

6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer.

6.2. That certificate shall contain at least the following information:

- (a) the name and identification number of the notified body;
- (b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
- (c) identification of the PPE covered by the certificate (type, model, manufacturer's reference);
- (d) a statement that the PPE complies with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II;
- (e) where harmonised standards have been fully or partially applied, the references of those standards or parts thereof;
- (f) where other technical specifications have been applied, their references;
- (g) where applicable, the performance level(s) or protection class of the PPE;
- (h) for made-to-measure PPE, the range of permissible variations of relevant parameters for made-to-measure PPE based on the approved basic model;
- (i) the date of issue and, where appropriate, the date(s) of renewal;
- (j) the date of expiry (a maximum of five years after the date of issue or the date of the last renewal);
- (k) any conditions attached to the issue of the certificate;
- (l) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in Article 18.

6.3. The EU type-examination certificate may have one or more annexes attached.

- 6.4. For made-to-measure PPE, if the person to whom the EU type-examination certificate was issued is not the manufacturer of the made-to-measure PPE:
- (a) the manufacturer of the made-to-measure PPE shall have the written authorisation of the certificate holder to use that certificate;
 - (b) the certificate holder shall provide the manufacturer of the made-to-measure PPE with the instructions referred to in point 12 of Annex III.
- 6.5. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
7. Review of the EU type-examination certificate
- 7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
- 7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.
- 7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.
- 7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate:
- (a) in case of a modification to the PPE referred to in point 7.2;
 - (b) in case of a change in the state of the art referred to in point 7.3;
 - (c) at the latest, before the date of expiry of the certificate.
- 7.5. The notified body shall examine the PPE and carry out any tests necessary to ensure that the PPE continues to fulfil the applicable essential health and safety requirements. In that case, it shall renew the EU type-examination certificate.
- 7.6. If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.
8. The notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

The notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto which it has refused,

withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

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

The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until 5 years after the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the PPE has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

ANNEX VI

Conformity to type based on internal production control

(Module C)

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.

For made-to-measure PPE the manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured made-to-measure PPE with the basic model described in the EU type-examination certificate and with the applicable essential health and safety requirements.

3. CE marking and EU declaration of conformity

3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements.

3.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.

A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

ANNEX VII

Conformity to type based on product verification

(Module F)

1. Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.

3. Application for product verification

Before placing PPE on the market, the manufacturer shall lodge an application for product verification with a single notified body of his choice.

The application shall include the following:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the identification of the PPE concerned.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

- (a) the technical documentation described in Annex III;
- (b) a copy of the EU type-examination certificate.

4. Verification of conformity

4.1. The notified body shall carry out appropriate examinations and tests in order to check the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.

4.2. The examinations and tests shall be carried out at least once a year, at random intervals determined by the notified body. The first examinations and tests shall be carried out no more than one year after the date of issue of the EU type-examination certificate.

4.3. An adequate random sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with

the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.

- 4.4. Where the notified body referred to in point 3 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.
- 4.5. If the examination and testing reveal that the production is not homogeneous or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.
5. Test report
 - 5.1. The notified body shall provide the manufacturer with a test report, and shall authorise the manufacturer to affix the notified body's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements.
 - 5.2. The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.
6. CE marking and EU declaration of conformity
 - 6.1. The manufacturer shall affix the CE marking, and, with the authorisation of the notified body referred to in point 3, the latter's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfy the applicable essential health and safety requirements.
 - 6.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.

A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.
7. If the notified body referred to in point 3 agrees, the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process.

8. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.

ANNEX VIII

Conformity to type based on quality assurance of the production process

(Module D)

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5 and 6, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the PPE concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the identification of the PPE concerned;
- (d) the documentation concerning the quality system.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

- (a) the technical documentation of the PPE described in Annex III;
- (b) a copy of the EU type-examination certificate.

3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination certificate and fulfils the applicable essential health and safety requirements.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
- (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
- (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
- (d) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc., and
- (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standards.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the field of PPE and technology concerned, and knowledge of the applicable essential health and safety requirements. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation of the PPE referred to in point 3.1 to verify the manufacturer's ability to identify the applicable essential health and safety requirements and to carry out the necessary examinations with a view to ensuring conformity of the PPE with those requirements.

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

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system.

The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.

It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfy the applicable essential health and safety requirements.

4. Surveillance under the responsibility of the notified body

4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

- 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
 - (a) the quality system documentation;
 - (b) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned.
- 4.3. The notified body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
- 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
5. CE marking and EU declaration of conformity
 - 5.1. The manufacturer shall affix the CE marking, and, with the authorisation of the notified body referred to in point 3.1, the latter's identification number to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfy the applicable essential health and safety requirements.
 - 5.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the product has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.

A copy of the EU declaration of conformity or a simplified EU declaration of conformity shall accompany every PPE.
6. The manufacturer shall, for a period ending 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:
 - (a) the documentation referred to in point 3.1;
 - (b) the information related to the change referred to in point 3.5, as approved;
 - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. The notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such quality system approvals refused, suspended or otherwise restricted.

The notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.
8. If the notified body referred to in point 3.1 agrees, the manufacturer may affix the notified body's identification number to the PPE during the manufacturing process.
9. Authorised representative

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

ANNEX IX

EU declaration of conformity

1. PPE (product, batch, type or serial number):
2. Name and address of the manufacturer or his authorised representative [The authorised representative must also give the business name and address of the manufacturer]:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of PPE allowing traceability; it may, where necessary for the identification of the PPE, include a colour image of sufficient clarity):
5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:
6. References to the relevant harmonised standards, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number)... performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate).
8. Where applicable, the PPE is subject to the conformity assessment procedure ... (either (Conformity to type based on product verification (Module F)) or (Conformity to type based on quality assurance of the production process (Module D)) ... under surveillance of the notified body ... (name, number).
9. Additional Information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

ANNEX X

Simplified EU declaration of conformity

The simplified EU declaration of conformity shall be provided as follows:

Hereby, [Name of manufacturer] declares that the PPE type [designation of type of PPE] is in compliance with the PPE Regulation (EU) No [XXXX/YYYY].
--

ANNEX XI**Correlation table**

<i>CORRELATION TABLE</i>	
Directive 89/686/EEC	This Regulation
Article 1(1)	Articles 1 and 2(1)
Article 1(2) and (3)	Article 3(1)
Article 1(4)	Article 2(2) and (3)
Article 2(1)	Article 4
Article 2(2)	Article 6
Article 2(3)	Article 7(2)
Article 3	Article 5
Article 4(1)	Article 7(1)
Article 4(2)	—
Article 5(1), (4), (5), (6)	—
Article 5(2)	Article 14
Article 6	Article 38
Article 7	—
Article 8(1)	Article 8(2) first subparagraph
Article 8(2) – (4)	Articles 17 and 18 and Annex I
Article 9	Articles 19, 23(1), 24, and 29(1)
Article 10	Annex V
Article 11(A)	Annex VII
Article 11(B)	Annex VIII
Article 12(1)	Article 15
Articles 12(2) and 13	Article 16
Article 14	—

Article 15	—
Article 16	—
Annex I	Article 2(2)
Annex II	Annex II
Annex III	Annex III
Annex IV	Article 16
Annex V	Article 23(2) – (11)
Annex VI	Annex IX