



Rules for the certification of Personal Protective Equipment in accordance with European Directive 89/686/EEC and subsequent amendments

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Chapter 1 - General

1 GENERAL

These Rules lay down the general criteria and procedures adopted by RINA for the EC certification of personal protective equipment in accordance with European Directive 89/686/EEC of 21 December 1989 as amended by Directives 93/68/EC of 22 July 1993, 93/95/EC of 29 October 1993 and 96/58/EC of 3 September 1996, hereafter referred to as the "PPE Directive".

2 FIELD OF APPLICATION

These Rules apply exclusively to the PPE listed in [4], which are within the scope of RINA notification.

3 DEFINITIONS AND ABBREVIATIONS

3.1 PPE

Personal protective equipment (PPE) covered by the PPE Directive, and consequently by these Rules, designed to be worn or held by an individual for protection against one or more health and safety hazards.

PPE also covers:

- a) 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;
 - b) a protective device or appliance combined with personal non-protective equipment worn or held by an individual for the execution of a specific activity;
- interchangeable PPE components which are used exclusively for such equipment.

3.2 PPE Directive

The set of provisions contained in Directive 89/686/EEC of 21 December 1989, as amended by subsequent Directives on PPE that are in force at the time such equipment are produced.

3.3 Categories of PPE

3.3.1 Category 0

Category 0 PPE is intended to mean:

- a) PPE covered by another Directive,
- b) PPE designed and manufactured specifically for use by the armed forces,
- c) PPE for self-defence,
- d) PPE for private use against
 - adverse atmospheric conditions
 - damp and water
 - heat,
- e) PPE for the protection or rescue of persons on vessels or aircraft, not worn all the time,
- f) motor cycle helmets and visors.

3.3.2 Category I

Category I PPE is intended to mean models of simple design where the Designer can certify that the user can himself assess the level of protection provided against the minimal risks concerned the effects of which, when they are gradual, can be safely identified by the user in good time.

This covers exclusively PPE intended to protect the wearer against:

- a) mechanical action whose effects are superficial,
- b) cleaning materials of weak action and easily reversible effects,
- c) risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C or to dangerous impacts,
- d) atmospheric agents of a neither exceptional nor extreme nature,
- e) minor impacts and vibrations which do not affect vital areas of the body and whose effects cannot cause irreversible lesions,
- f) sunlight.

3.3.3 Category II

Category II PPE is intended to mean all PPE which is not Category 0, I or III.

3.3.4 Category III

Category III PPE is intended to mean products 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.

3.4 Notified body

A notified body is an organisation designated by the competent national administration of one of the Member States of the European Community to carry out the activities of certification of all or part of the PPE covered by the PPE Directive.

3.5 Essential requirements

Essential requirements are the minimum indispensable of a general nature which the PPE is to fulfil in order to achieve the objectives of the PPE Directive.

Such requirements provide basic criteria which:

- derive from particular hazards inherent in the product (for example poor physical and mechanical resistance, risk of short-circuit, inflammability, etc.)
- refer to the product or its performance (for example requirements concerning the materials, design, manufacture and specific use intended, etc.)
- lay down the main objectives of protection, for example by means of adequate information.

Only products that fulfil the essential requirements can be placed on the market and/or brought into service.

The essential requirements applicable to the types of equipment for which RINA is the body of which notification is given are laid down in Chapter 2.

3.6 Harmonised standards

Harmonised standards are those which have been agreed by all the Member States of the European Community. They achieve the *status* of harmonised standards only after their publication in the Official Journal of EU. Harmonised standards are adopted within the national legislative framework of the different countries in the Community.

Harmonised standards are issued by the European standardisation bodies CEN, CENELEC and ETSI.

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4 SCOPE OF RINA NOTIFICATION

Among the types of PPE covered by the PPE Directive the followings are those for which RINA is notified:

- 1) LIFEJACKETS AND BUOYANCY AIDS
- 2) BUOYANCY COMPENSATORS
- 3) SELF-CONTAINED OPEN-CIRCUIT UNDERWATER BREATHING APPARATUS
- 4) SELF-CONTAINED CLOSED-CIRCUIT UNDERWATER BREATHING APPARATUS
- 5) OPEN-CIRCUIT UNDERWATER BREATHING APPARATUS
- 6) CLOSED -CIRCUIT UNDERWATER BREATHING APPARATUS
- 7) DIVING ACCESSORIES
- 8) DECK SAFETY HARNESS AND LINE FOR USE ON RECREATIONAL CRAFT
- 9) DIVING SUITS (DRY AND WET SUITS)
- 10) IMMERSION SUITS

5 CERTIFICATION PROCEDURES

5.1 General

The certification procedures which are to be applied to a PPE model before it is placed on the market and brought into service depend on the category of the PPE in accordance with the criteria laid down by the Working Party on PPE set up by the Commission under number 98/37/CE.

5.2 Type of certification required

5.2.1 Category I PPE

The Manufacturer or his authorised representative established in the Community is to draw up a Declaration of Conformity, using the form laid down in Annex 1, with a view to its submission to the competent authorities. The involvement of a notified body is not required for this purpose.

5.2.2 Category II PPE

The Manufacturer or his authorised representative established in the Community is to draw up a Declaration of Conformity, using the form laid down in Annex 1, once the relevant EC type-approval certificate has been issued by a notified body.

5.2.3 Category III PPE

The Manufacturer or his authorised representative established in the Community is to draw up a Declaration of Conformity, using the form laid down in Annex 1, once the relevant EC type-approval certificate has been issued by a notified body and the latter or another notified body has inspected the manufacturing process.

5.3 PPE Categories within the scope of RINA notification

With reference to item [4], the PPE listed in 1) and 2) are considered Category II, the PPE listed from 3) to 10) and in 12) are considered Category III, while the PPE in 11) may be either Category II or III depending on the temperature at which the equipment is used.

6 PRESUMPTION OF CONFORMITY

It is not essential that a particular PPE model should be manufactured in accordance with harmonised standards, provided that it complies with the essential requirements mentioned in [3.5]. In such case the design and test criteria are to be agreed between the Manufacturer and RINA.

However, where a harmonised standard covers all the aspects considered in the essential requirements, the application of this standard to the design and testing of a PPE model is sufficient to ensure the presumption of conformity of such PPE to the Directive, without further consideration.

The list the harmonised standards in force is shown in the last edition of document C of the Official Journal of EU at the link: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/personal-protective-equipment/index_en.htm

Chapter 2 - Type approval

1 GENERAL

This Chapter describes the procedure adopted by RINA to establish the conformity of a PPE prototype to the PPE Directive and for the consequent issue of an EC Type Examination Certificate of Category II and III PPE.

2 APPLICATION

Prior to proceeding with the series manufacture of a PPE model, the Manufacturer is to submit an application for certification; such application is to include the name and address of the Manufacturer, the place of manufacture and the identification of the type(s) of PPE to be manufactured (see Annex 3).

The application is to comprise:

- a) the technical documentation referred to in [3.1];
- b) an appropriate number of specimens of the model to be approved in order to conduct the tests referred to in [3.2].

In the application the Manufacturer is to state whether he intends, in relation to the production control methods for Category III PPE manufactured:

- a) to ask RINA to perform production surveillance of one or more PPE models for which EC type examination is requested,
- b) and, if so, whether
 - to adopt the procedure in Chapter 3, item [2] – Product quality control,
 - to adopt the procedure in Chapter 3, item [3] – EC production quality assurance system

3 EC TYPE EXAMINATION

3.1 Technical documentation

3.1.1 Composition of the technical documentation

The technical documentation regarding the manufacture of PPE comprises:

- detailed and complete constructional drawings of the PPE;
- technical specifications with indication of the design procedures used to fulfil the essential safety requirements;
- any results of prototype tests related to the fulfilment of the essential safety requirements;
- the monitoring and test methods used at the production facility.

The technical documentation is to be supplemented by information notes supplied by the Manufacturer of the PPE, provided at least in the official language(s) of the Member State(s) of destination and containing the following information, as far as applicable:

- a) the name and address of the Manufacturer or of his authorised representative established in the Community;
- b) the instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by the Manufacturer must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;

- c) suitable PPE accessories and the characteristics of appropriate spare parts and permitted attachment mechanisms;
- d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;
- f) the type of packaging suitable for transport of PPE;
- g) the significance of any markings on PPE;
- h) maximum design depth of immersion;
- i) other safety devices required, with reference to the risk of use;
- j) temperature conditions;
- k) visibility;
- l) types of activities that can be performed;
- m) checks to be carried out before use;
- n) methods of attachment and removal;
- o) other recommendations at the discretion of the Manufacturer.

3.1.2 Examination of the technical documentation

RINA will examine the documents to verify that they comply with the requirements of the PPE Directive, indicated in [4], and with the provisions laid down in the applicable harmonised standard.

Where a Manufacturer has not applied or has only partly applied the harmonised standard, RINA will first verify the conformity of the technical specifications used by the Manufacturer to the essential requirements and subsequently check the conformity of the technical documentation of production to the technical specifications.

3.2 Type examination

3.2.1 Examination of the specimens and issue of the certificate

RINA will examine the specimens sent with the technical documentation and verify that they have been produced in accordance with the Manufacturer's technical file.

Following this, the specimens and/or their components will be subjected to the relevant and/or necessary tests, in accordance with the applicable harmonised standard or, where a harmonised standard has not been applied or has only been partly applied, in accordance with the criteria agreed between the Manufacturer and the RINA to verify the conformity with the essential requirements. Subject to the satisfactory outcome of the tests conducted, RINA, by means of the Technical Head of PPE CE certification process, will issue to the Manufacturer an EC Type Examination Certificate for the PPE examined. This certificate and its annexes will reproduce the findings of the tests carried out, and incorporate the descriptions and drawings necessary for the identification of the approved PPE model.

3.2.2 Execution of tests and Testing Laboratories

Type tests are to be performed at the Laboratories hereafter defined:

- a) the RINA Laboratory;
- b) independent laboratories;
- c) laboratories belonging to an Administration;
- d) laboratories other than those in a), b) and c), located in test rooms and/or production facilities belonging to

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the Manufacturer or designated by the latter as a location for type testing.

Such laboratories are to show that they:

- operate a quality system in accordance with ISO 17025 and therefore guarantee that testing is conducted in conformity with international instruments,
- are not involved, either directly or through the employer, in the design and manufacture of the product tested as this could affect their impartiality and independence.

RINA accepts type testing carried out by independent laboratories that:

- are certified and/or recognised by a full member of ILAC (International Laboratory Accreditation Cooperation) for the type tests concerned. A complete updated list of member organisations of ILAC can be viewed at www.ILAC.org,
- are certified and /or recognised by an Administration or by another IACS MED Notified Body.

Laboratories that have not obtained certification or recognition as above may be accepted subject to certification or assessment by RINA in accordance with its "RULES FOR THE ASSESSMENT OF TESTING LABORATORIES".

Laboratories as per item d) above may be accepted when they are assessed by RINA according to its "RULES FOR THE ASSESSMENT OF TESTING LABORATORIES", provided that testing is carried out with RINA personnel in attendance in order to ensure impartiality and objectivity.

3.2.3 PPE not passing the type examination

Where the outcome of the tests is unsatisfactory, RINA will notify the Manufacturer of this, indicating the relevant corrective actions required.

If RINA refuses to issue an EC Type Examination Certificate, it will notify the applicant of this fact, setting out the reasons for the decision, and also inform the other notified bodies.

The Manufacturer may not submit a new application for certification of the PPE until any changes necessary to fulfil the prescribed requirements have been made.

The new application is to include all the documents referred to in [3.1].

4 ESSENTIAL REQUIREMENTS

4.1 General requirements applicable to all PPE

PPE is to provide adequate protection against all risks encountered.

4.2 Design principles

4.2.1 Ergonomics

PPE is to 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.

4.2.2 Levels and classes 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 normal performance of the activity.

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.

4.2.3 Innocuousness of PPE

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

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

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

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

4.2.4 Comfort and efficiency

PPE is to 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. For this purpose, it is to be possible to optimise PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

PPE is to be as light as possible without prejudicing design strength and efficiency.

Apart from the specific additional requirements which it is to satisfy in order to provide adequate protection against the risks in question (see [4.4]), PPE is to be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

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

4.3 Additional requirements common to several classes or types of PPE

4.3.1 PPE incorporating adjustment systems

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

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

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

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4.3.3 PPE for the face, eyes and respiratory tracts

Any restriction of the user's field of vision or sight by PPE for the face, eyes or respiratory tract is to be minimised.

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

If necessary, they are to be treated or provided with facilities to prevent moisture formation.

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

4.3.4 PPE subject to ageing

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

If a Manufacturer is unable to give an undertaking with regard to the useful life of PPE, his notes are to 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 PPE performance is likely to be caused by ageing resulting from the periodical use of a cleaning process recommended by the Manufacturer, the latter is, if possible, to affix a mark to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded; failing that, the Manufacturer is to give this information in his notes.

4.3.5 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 is to possess an appropriate resistance threshold above which a constituent part will break and eliminate the danger.

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

These PPE classes are to be so designed and manufactured as to minimise the time required for attachment and (or) removal.

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

4.3.7 PPE for use in very dangerous situations

The information notes supplied by the Manufacturer together with PPE for use in very dangerous situations are to 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.

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

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

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

Any PPE components which can be adjusted or removed by the user for the purpose of replacement are to be so designed and manufactured as to facilitate manual adjustment, attachment and removal.

4.3.9 PPE for connection to another, external complementary device

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

4.3.10 PPE incorporating a fluid circulation system

If PPE incorporates a fluid circulation system, the latter is to 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.

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

The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or categories of PPE are to preferably take the form of harmonised pictograms and to remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks are to be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks incorporate words or sentences, the latter are to appear in the official language(s) of the Member State where the equipment is to be used.

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

4.3.12 PPE in the form of clothing capable of signalling the user's presence visually

PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled is to 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.

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4.3.13 'Multi-risk' PPE

All PPE designed to protect the user against several potentially simultaneous risks is to be so designed and manufactured as to satisfy, in particular, the essential requirements specific to each of those risks.

4.4 Additional requirements specific to particular risks

4.4.1 Protection against impact caused by falling or projecting objects and collision of parts of the body with an obstacle

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

4.4.2 Falls

a) Prevention of falls due to slipping

The outsoles for footwear designed to prevent slipping are to 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.

b) Prevention of falls from a height

PPE designed to prevent falls from a height or their effects is to incorporate a body harness and an attachment system which can be connected to a reliable anchorage point. It is to be designed so that under the foreseeable conditions of use the vertical drop of the user is minimised to prevent collision with obstacles and the braking force does not, however, attain the threshold value at which physical injury or the tearing or rupture of any PPE component which might cause the user to fall can be expected to occur.

It is also to ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.

The Manufacturer's notes are to specify in particular all relevant information relating to:

- the characteristics required for the reliable anchorage point and the necessary minimum clearance below the user;
- the proper way of putting on the body harness and of connecting the attachment system to the reliable anchorage point.

4.4.3 Mechanical vibration

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

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

4.4.4 Protection against (static) compression of part of the body

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

4.4.5 Protection against cold

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

a) PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold are to 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 are to 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 are also to possess sufficient mechanical-impact absorbency (see [4.4.1]).

b) Complete PPE ready for use

Under the foreseeable conditions of use:

- the flux transmitted by PPE to the user is to 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;
- PPE is as far as possible to 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 is to adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The Manufacturer's notes accompanying each PPE

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model intended for brief use in low-temperature environments are to provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

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

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

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

Under the foreseeable conditions of use:

- a) PPE is, without prejudice to its satisfactory operation, to 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 are also to satisfy one or more of the following additional requirements:

- 1) it is to have all the inflation devices referred to in b) above, and a light or sound-signalling device;
- 2) it is to have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- 3) it is to 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.

4.4.7 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 is to enable him, in particular, to swim or take action to escape from danger or rescue other persons.

4.4.8 Safety devices for diving equipment

- a) The breathing equipment is to 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.
- b) Where the foreseeable conditions of use so require, the equipment is to comprise:
 - a suit which protects the user against the pressure resulting from the depth of immersion (see [4.4.4]) and/or against cold (see [4.4.5]);
 - an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see [4.3.7]);
 - a life-saving suit enabling the user to return to the surface (see [4.4.7]).

Chapter 3 - Category III PPE production control

1 GENERAL

1.1 Articles 11A and 11B of the PPE Directive

The production of Category III PPE is to be inspected by a notified body before as long as such equipment is manufactured and marketed.

Such inspections may comprise either random checks of the quality of the final product on samples taken from the production lines or from the market, or monitoring of the Manufacturer's production quality assurance system applied to the certified product. Since the two inspection procedures are defined in Articles 11A and 11B of the PPE Directive, they are generally referred to commonly as "Checks according to Article 11A" and "Checks according to Article 11B", respectively.

1.2 Equivalence of the checks

The choice of whether to use the supervision procedure according to Article 11a or according to 11b is left to the Manufacturer, provided that he has implemented an effective and reliable quality assurance system.

In any event, irrespective of which inspection procedure is adopted, when the outcome is satisfactory the final certification is equivalent in all respects; the fact that one method is chosen rather than the other has no bearing whatsoever on the quality of the equipment certified using such method.

2 CHECKS ACCORDING TO ARTICLE 11A

2.1 Preliminary check

Following the issue of the **EC Type Examination Certificate** for a PPE model, a RINA Surveyor will examine an adequate set of samples taken from the production line and subject them to some or all of the tests prescribed in the applicable harmonised standards or, failing this, to those agreed by the Manufacturer and RINA upon submission and acceptance of the application as being necessary to establish the conformity of the samples with the type(s) described in the EC Type Examination certificate.

Subject to the satisfactory outcome of such tests, RINA, by means of the Technical Head of PPE CE certification process, will issue an **EC Final Product Conformity Certificate**, which is valid for one year.

Where the test samples used for the type examination were chosen by a RINA Surveyor from the production line (i.e. they were not prototypes manufactured specially for the tests), the tests conducted for the issue of the **EC Type Examination Certificate** can also be considered valid for the preliminary check of production. In this case the issue of the **EC Final Product Conformity Certificate** is concomitant with that of the type examination certificate.

2.2 Renewals

The **EC Final Product Conformity Certificate** is subject to annual renewal.

Upon expiry of the certificate, within a time window from the anniversary date of the issue of the first certificate and two months before, a RINA Surveyor will take an adequate number of samples from the production line and/or from the market in agreement with the

Manufacturer and will subject them to the relevant tests.

Subject to the satisfactory outcome of the tests, RINA will issue a new certificate.

RINA reserves the right to make unannounced visits to the Manufacturer, in addition to those scheduled, on the basis of the results of the checks and of market feedback.

2.3 Unsatisfactory tests

In the event of unsatisfactory test results, RINA will consider the nature of the fault detected, repeat some or all of the tests and determine any corrective actions in agreement with the Manufacturer.

In the most serious cases or whenever it is found that the Manufacturer cannot ensure homogeneous production, RINA will suspend the certification and inform the Italian Ministry of Industry so that the non-conforming PPE is withdrawn from the Community Market.

3 CHECKS ACCORDING TO ARTICLE 11B

3.1 General

Within the framework of this procedure the Manufacturer is to use a quality system for the manufacturing process, including inspections and tests during production and of the final product. A system which is certified by RINA or by an accredited certification body against EN ISO 9001:2008 standard is presumed compliant. If the quality system is not certified as described in the above, RINA proceeds with its evaluation to establish if it satisfies the requirements of the PPE Directive. RINA is to be authorised to have access for the purpose of supervising this system.

3.2 QUALITY SYSTEM

All the elements, requirements and provisions adopted by the Manufacturer are to be thoroughly documented in the form of written procedures and instructions. The quality system documentation is to enable consistent interpretation of quality programmes, plans, manuals and documents.

The quality system documentation is to include in particular an adequate description of:

- a) the quality objectives, the organisation chart, the responsibilities of department heads and their powers in respect of product quality;
- b) the manufacturing methods, the quality control and quality assurance techniques, the processes and systematic actions which it is intended to apply;
- c) the tests which are to be carried out before, during and after manufacture, with indication of their intended frequency;
- d) the quality documentation such as audit reports, test and calibration data, reports concerning the qualifications of relevant personnel, etc.;
- e) the means used to verify constantly that the product has achieved the required quality level and that the quality system operates efficiently.

Chapter 3 - Category III PPE production control

3.3 Assessment criteria for quality assurance systems for the purposes of certification of PPE

3.3.1 Major findings

A major finding is:

- a) any finding relative to a non-conformity that has caused the placement on the market of a product with defects such as to prevent or impair its use in complete safety for its intended purpose;
- b) any finding relative to a failure of the quality assurance/control system which, judging from common sense and experience, might cause faults in the quality system such as to give rise to the concrete risk of manufacturing PPE with defects similar to those described in a) above;
- c) a minor finding detected in previous audits relative to a non-conformity which has not been satisfactorily corrected;
- d) an alteration to the design, manufacturing processes and/or materials of certified products that has not been authorised by RINA.

3.3.2 Minor findings

A minor finding is:

- a) any finding relative to a non-conformity that has caused the placement on the market of a product with defects which are not as serious as those described in [3.3.1] a);
- b) any finding relative to a failure of the quality assurance/control system which, judging from common sense and experience, might cause faults (in short time) which are not such as to give rise to the concrete risk of manufacturing products with defects similar to those described in [3.3.1] a).

For example:

- problems related to quality records;
- problems related to the Company's management system that have no direct bearing on the product.

3.3.3 Assessment of the quality system

The outcome of a quality system is deemed positive when the audit does not reveal major findings.

The causes of a major non-conformity are to be identified and corrected by the Manufacturer. In general, to end a major non-conformity an audit is necessary in order to assess the effectiveness of the corrective actions adopted, whereas a document inspection may be sufficient to end a minor non-conformity.

In any event, the final assessment concerning the actions required to end a non-conformity is left to the discretion of RINA, which will from time to time decide whether to hold an audit at the Manufacturer's facilities or simply to inspect the documentation.

Where the causes that led to a major non-conformity cannot be effectively removed within the agreed period, the audit is considered "failed" and the entire quality system is to be subjected to reassessment..

3.4 Audits of companies with quality systems not certified by rina

3.4.1 Documentation to be submitted

Prior to the audit the Manufacturer is to submit to RINA the following documentation:

- a) quality control plans or equivalent,
- b) the main quality procedures that may affect the products to be certified,
- c) all procedures regarding the manufacture and testing of the products to be certified,
- d) a pledge to fulfil the obligations arising from the quality system and to maintain and apply it effectively,
- e) the technical documentation pertaining to the type approval and a copy of the EC Type Examination Certificate.

Where this certificate has been issued by a notified body other than RINA, RINA may request the Manufacturer to submit the complete documentation (including drawings and test reports) on the basis of which the other notified body issued the type examination certificate.

RINA will inspect the documentation and inform the Manufacturer whether it is sufficient or whether further documents and/or type examination are necessary before the product can be certified and marked in accordance with these Rules.

3.4.2 Surveillance cycles

The issue and retention of the certificate is subject to the satisfactory outcome surveillance cycles consisting of the following surveys:

- a) first assessment of the quality assurance system and of the production line(s) for the product(s) to be certified;
- b) periodical assessments of the quality assurance system;
- c) periodical assessments of the production line(s) for the product(s) to be certified.

The assessments in b) and c) may be conducted at the same time. The assessment schedule is agreed by RINA and the Manufacturer at the beginning of the certification process as a function of the complexity of the equipment and of the quality assurance system adopted by the Manufacturer. In any event, at least one assessment is to be carried out during the period of validity of the certificate.

RINA reserves the right to perform unannounced surveys in addition to those mentioned above.

3.4.3 First assessment

The aim of the first assessment is to evaluate the quality assurance system adopted by the Manufacturer with special reference to the production line(s) for the model(s) to be certified.

In general, as far as possible, this assessment is to be scheduled so that it can be performed during the actual manufacturing of the model(s) to be certified.

The surveillance is conducted using criteria similar to those described in the Rules for the Certification of Quality Systems.

Within the scope of the surveillance assessment of the quality system, particular attention is to be paid to the following documentation pertaining to the model(s) to be certified:

Chapter 3 - Category III PPE production control

- quality plans regarding the products to be certified;
- internal audit reports;
- reports of tests carried out on the manufactured products;
- calibration certificates for the testing equipment.

In the course of the assessment, as far as possible the tests performed by the Manufacturer both during the various phases of manufacturing and for acceptance of the product(s) are to be supervised in order to ensure that they comply with the applicable requirements, in accordance with the assessment criteria laid down in [3.3].

Upon completion of their intervention, the RINA Surveyors will prepare a survey report and leave a copy with the Manufacturer.

3.4.4 Issue of the certificate

If the outcome of the assessment is deemed satisfactory, RINA, by means of the Technical Head of PPE CE certification process, will issue to the Manufacturer an **EC Certificate of Conformity of Production** for each model certified. Reference is made in this certificate to the **EC Type Examination Certificate(s)** for the models concerned.

3.4.5 Periodical surveillance

The aim of periodical surveillance is to verify that the quality assurance system adopted by the Manufacturer with special reference to the production line(s) for the product(s) certified is maintained over time.

When periodical surveillance becomes due, RINA and the Manufacturer agree on the date and procedures of the relevant assessment.

Within the scope of the assessment in 3.4.2 b) for the surveillance of the quality system, aspects of the quality control system are sampled and inspected on a rotation basis.

Within the scope of the assessment in 3.4.2 c) for the surveillance of the production line, the following aspects of the models certified are always to be inspected, for each model for which an **EC Certificate of Conformity of Production** has been issued:

- a) internal audit reports;
- b) quality plans regarding the products certified, or equivalent documents;
- c) reports of tests carried out on the manufactured products;
- d) calibration certificates for the testing equipment.

If possible, in the course of the assessments the tests performed by the Manufacturer both during the various phases of manufacturing and for acceptance are to be supervised in order to ensure that they comply with the requirements.

3.4.6 Confirmation or suspension of the certification

Upon completion of his intervention, the RINA Surveyor will prepare a survey report, leave a copy with the Manufacturer and endorse the **EC Certificate of Conformity of Production**, confirming its validity until the date of the next scheduled periodical assessment.

In the event that major findings as defined in [3.3] are detected, RINA will notify the Manufacturer of the reasons for which it is not possible to endorse the certificate and immediately suspend the certification of

all those products which may be affected by the deviation found, indicating the serial number from which the suspension applies and/or any other information needed to identify the products suspended. The suspension will end upon completion of the corrective action.

The applicant may not submit a new application for surveillance until any changes to the quality system necessary to fulfil the prescribed requirements have been made.

3.5 Companies with quality systems certified by RINA

3.5.1 Documentation to be submitted

In this case no company quality system documentation needs to be sent, except for the quality plans for each model certified.

3.5.2 Issue of the certificate

The quality control plans are to be examined by RINA. Where the foregoing plans are deemed satisfactory and complete, an initial assessment is not necessary, insofar as the product(s) is/are accepted on the basis of the company quality system certificate issued by RINA, provided that the first surveillance assessment due for the purpose of quality system certification is due within six months from the date of issue of the Certificate of Conformity. Therefore, in this case the **EC Certificate of Conformity of Production** is automatically issued by RINA according to the procedures and conditions specified in [3.4.4].

Where quality control plans are not submitted by the Manufacturer or are not deemed satisfactory and complete or the first periodical assessment due for the purpose of quality system certification is due more than six months after the date of issue of the Certificate of Conformity, it is necessary to conduct an initial assessment at least equivalent to that described in [3.4.2] c). In this case the **EC Certificate of Conformity of Production** is issued by RINA upon completion of the assessment, provided the latter is deemed satisfactory. Where the outcome of the assessment is deemed unsatisfactory, the certificate is not issued until all the causes of the major non-conformities have been removed.

3.5.3 Periodical surveillance, confirmation or suspension of the certification

In principle periodical surveillance is to be conducted and controlled in accordance with the provisions of [3.4.5] and [3.4.6]. Irrespective of its frequency, the content of periodical surveillance will be equivalent to the assessment described in [3.4.2] c).

Annual periodical surveillance is to coincide, as far as possible, with the dates of periodical assessments for quality system certification.

3.6 Companies with quality systems certified by a recognised body other than RINA

In principle companies with quality systems certified by a recognised body other than RINA are treated as described in [3.4]. However, for such companies

Chapter 3 - Category III PPE production control

consideration may be given at the discretion of RINA to some relaxation of the annual surveillance and assessment surveys.

3.7 Companies with PPE already certified by RINA

Where a company which produces one or more models certified by RINA in accordance with Article 11b applies for the certification and marking of other models, all the provisions in Chapter 2 are to be applied with regard to the issue of the **EC Type Examination Certificate**.

At the time of issue of the above certificate RINA will decide whether or not to conduct an initial assessment applying a criterion similar to that described in [3.5] for the purpose of the **EC Certificate of Conformity of Production**. Following this, the periodical assessments for the new model are scheduled to coincide with those due for the other models certified; in this way the checks necessary for certification of each model are performed at the same time.

Chapter 4 - Marking, withdrawals

1 MARKING

1.1 CE marking

Category II products which conform to the relevant international provisions and have been certified in conformity with these Rules are to be indelibly marked in the form shown in Annex 4.

1.2 Affixing of the CE marking

The CE marking is to be affixed by the Manufacturer or his authorised representative established in the Community to each piece of PPE that has satisfied the relevant certification procedure. If PPE is too small to allow all or part of the CE marking to be affixed to the equipment, such marking is to be affixed to the packaging and to the Manufacturer's notes.

1.3 Category III PPE

For Category III PPE certified by RINA, the CE marking is to be followed by RINA's identification number as the notified body.

RINA's identification number is **0474**.

2 WITHDRAWALS

2.1 Suspension of the authorisation to affix the CE marking

Qualora durante le visite periodiche vengono riscontrate Where serious deficiencies are detected during periodical assessments, the authorisation to affix the CE marking is immediately suspended until such time as the problem is removed.

Where, in the case of Category III models certified in accordance with Article 11b of the PPE Directive, the deficiencies concern aspects of the quality assurance system, the equipment manufactured during the period necessary for the application of the relevant corrective actions may be marked and placed on the market provided it is subjected to the checks as per Article 11a of the PPE Directive, provided the Manufacturer submits an application to this end and provided the checks are conducted with a frequency, agreed by RINA and the Manufacturer, which is greater than that normally foreseen for such type of certification.

2.2 Withdrawal of certificates

Certificates issued by RINA for PPE may be withdrawn where there are serious deficiencies on the part of the Manufacturer, such as:

- a) a major non-conformity of the final product or the manufacturing process with respect to the technical documentation submitted to RINA;
- b) serious defects detected in service;
- c) significant modifications made to the product without informing RINA;
- d) non-payment or overdue payment of fees.

The validity of the certification may also be withdrawn in the event of changes to the provisions and/or requirements applicable to the product which the Manufacturer is unable to comply with.

Withdrawal of the validity of the certification is to be communicated to the Italian Ministry of Industry for subsequent communication to the European Community.

Annex 1 - Facsimile of the declaration of conformity

MODEL DECLARATION OF CONFORMITY

The Manufacturer or his authorised representative established in the Community: ⁽¹⁾

declares that the new PPE described hereafter: ⁽²⁾

is in conformity with the provisions of Directive 89/686/EEC
and is identical to the PPE which is the subject of EC Certificate of Conformity CE n° _____ issued by: ⁽³⁾

on

is subject to the procedure set out in Article 11 point A or point B of Directive 89/686/EEC under the supervision of the notified body: ⁽⁴⁾

Place and date: _____ on _____

Signature ⁽⁵⁾

- (1) Business name and full address; authorised representatives are also to give the business name and address of the Manufacturer
- (2) Description of the PPE (make, type, serial number, etc.)
- (3) Name and address of the approved body
- (4) Delete whichever is inapplicable
- (5) Name and position of the person empowered to sign on behalf of the Manufacturer or his authorised representative

Annex 2 - Facsimile of the application for certification

MODEL APPLICATION FOR CERTIFICATION

**DOMANDA PER LA VALUTAZIONE DELLA CONFORMITA' DI DPI ALLA DIRETTIVA EUROPEA 89/686/CEE
E SUCCESSIVI EMENDAMENTI
APPLICATION FOR ASSESSMENT OF CONFORMITY OF PPE TO EUROPEAN DIRECTIVE 89/686/EEC
AND SUBSEQUENT AMENDMENTS**

**FABBRICANTE O SUO RAPPRESENTANTE AUTORIZZATO
MANUFACTURER OR AUTHORISED REPRESENTATIVE**

Ragione sociale Name			
Indirizzo Address			
Persona riferimento Reference person			
Partita IVA Registration Number	Telefono Telephone	Fax	e-mail

**NOME DEL FABBRICANTE E DEL SITO PRODUTTIVO
(se differente da quanto sopra)
NAME OF MANUFACTURER AND PRODUCTION SITE
(if different from above)**

Ragione sociale Name			
Indirizzo Address			
Persona riferimento Reference person			
Partita IVA Registration Number	Telefono Telephone	Fax	e-mail

**DESCRIZIONE DEL DPI
PPE DESCRIPTION**

Denominazione commerciale Brand name	
Tipo di prodotto Product type	
Norme di riferimento Reference standards	

**CERTIFICAZIONE RICHIESTA
REQUESTED CERTIFICATES**

Certificato di esame CE del tipo EC type examination certificate (Article 10)	Certificato di conformità CE del prodotto finito (Articolo 11A) EC final product conformity certificate (Article 11A)	Certificato di conformità CE della produzione (Articolo 11B) EC production conformity certificate (Article 11B)
(barrare dove applicabile) (tick where applicable)		

L'AZIENDA DICHIARA DI NON AVER PRESENTATO ANALOGA DOMANDA DI CERTIFICAZIONE PER GLI EQUIPAGGIAMENTI SOPRA CITATI AD ALTRO ORGANISMO NOTIFICATO

THE COMPANY DECLARES THAT IT HAS NOT SUBMITTED A SIMILAR APPLICATION FOR THE CERTIFICATION OF THE ABOVE INDICATED EQUIPMENT TO ANOTHER NOTIFIED BODY

DATA: _____ TIMBRO E FIRMA: _____
DATE: _____ STAMP AND SIGNATURE: _____

Annex 2 - Facsimile of the application for certification

L'Azienda si impegna a:

- rispettare le prescrizioni contenute nei documenti RINA "Specifiche per la certificazione di dispositivi di protezione individuale", "Norme per la certificazione di dispositivi di protezione individuale secondo la Direttiva Europea 89/686/CEE e successivi emendamenti" (disponibile sul sito web del RINA), nelle "Norme per Il riconoscimento dei Laboratori di Prova" (disponibile sul sito web del RINA), nelle condizioni generali di contratto riportate nel Form RETAIL e nelle norme armonizzate o specifiche tecniche applicabili;
- dare la necessaria assistenza ai tecnici del RINA e, ove richiesto, anche agli Ispettori di ACCREDIA e/o dell'Amministrazione competente durante le visite ai fini della certificazione e della sorveglianza;
- rispettare le condizioni economiche contenute nel documento RINA n. del e corrispondere al RINA i diritti relativi all'attività di certificazione, con il rimborso delle spese sostenute a tale scopo, anche nel caso in cui la procedura di certificazione non si concluda con l'emissione degli atti di certificazione per responsabilità del richiedente.

The Manufacturer shall:

- *comply with the requirements of RINA documents "Specification for the Certification of Personal Protective Equipment", "Rules for the Certification of Personal Protective Equipment in accordance with European Directive 89/686/EEC and subsequent amendments" (available on RINA website), "Rules for the recognition of test laboratories" (available on RINA website), in the terms and conditions shown on the Form RETAIL and in the applicable harmonized standards or technical specifications,*
- *supply RINA Surveyors and, if any, ACCREDIA Inspectors and/or competent administration with the necessary assistance during their attendance at the facility for the surveys and the certification;*
- *respect the economic conditions contained in RINA document No. of, pay RINA the fees relative to the certification activities and reimburse the expenses incurred to this end, even in the event that the certification process does not conclude with the issuance of a certificate due to applicant responsibility.*

L'Azienda autorizza il RINA a pubblicare i dati inclusi nei certificati relativi ai prodotti oggetto di questa domanda

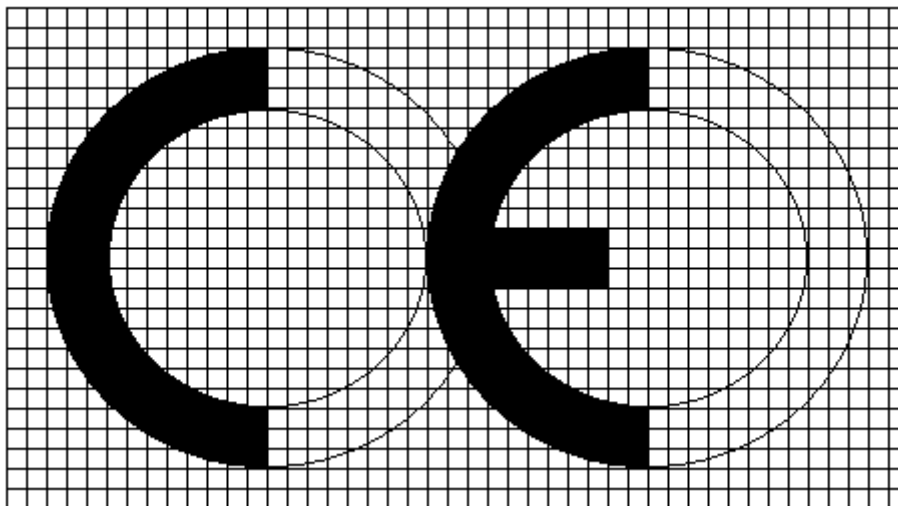
The Manufacturer authorises RINA to publish the data contained in the certificates relative to the products which are the subject of this application.

TIMBRO E FIRMA: _____
STAMP AND SIGNATURE

Annex 3 - CE marking

The CE conformity marking is to consist of the initials "CE" as shown in Figure 1.

Figura 1



If the CE marking is reduced or enlarged the proportions given in the above graduated drawing are to be respected.

The various components of the CE marking are to have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale PPE.

In the case of Category III equipment whose production is certified by RINA, the CE marking is to be followed by the number **0474**.

The CE marking may be affixed in any position provided that there is no risk of confusion with any other marks or inscriptions affixed by the Manufacturer.