



Rules for the certification of Personal Protective Equipment in accordance with Regulation (EU) 2016/425

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RINA
Via Corsica 12
16128 Genova - Italy

tel +39 010 53851
fax +39 010 5351000
web site : www.rina.org

Technical Rules

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CHAPTER 1 – GENERAL

1.1

These Rules lay down the procedures adopted by RINA for the Conformity Assessment of personal protective equipment (hereinafter referred to as 'PPE') in accordance with the requirements of Regulation (EU) 2016/425, (hereinafter referred to as 'PPE Regulation' or 'Regulation') and the modalities to be observed by the Organisations to request, obtain and maintain this certification.

1.2

All Organisations can apply for certification irrespective of whether they belong to any Association or Group or not. For the certification activity RINA will apply its own tariff lists, ensuring their fair and consistent application.

1.3

The certification issued by RINA refers to the personal protective equipment specified in the certificate and manufactured by the applicant Organisation, where the term Organisation indicates a company, enterprise, firm, body or association, legally recognized or not recognized, public or private, with its own functions and administration or a natural person. In the presence of Organisations with several operative units, a single operative unit can be considered as an Organisation.

1.4

The information acquired during the certification activity is considered and treated as confidential, unless otherwise provided for by the law or in the presence of justified requests by the competent authorities.

1.5

The terms used in these Standards are the same as those used in the PPE Regulation.

1.6

RINA identification number to be applied to the personal protective equipment covered by the certification issued by RINA is no. 0474.

This number must be affixed in accordance with the PPE Regulation.

CHAPTER 2 – FIELD OF APPLICATION

2.1

These Rules apply exclusively to the PPE listed in Chapter 3, which is within the scope of RINA notification.

CHAPTER 3 – SCOPE OF RINA NOTIFICATION

3.1

Among the types of PPE covered by the PPE Regulation, RINA is notified for only the PPE specified in the list here below:

- 1) LIFEJACKETS AND BUOYANCY AIDS
- 2) BUOYANCY AIDS
- 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) DECK SAFETY HARNESS AND LINE FOR USE ON RECREATIONAL CRAFT
- 8) DIVING SUITS (DRY AND WET SUITS)
- 9) IMMERSION SUITS

3.2

The categories of PPE are found in Regulation 2016/425 and related guides for its application in the EU website.

<http://ec.europa.eu/growth/sectors/mechanical-engineering/personal-protective-equipment>.

CHAPTER 4 – LEGAL REQUIREMENTS

4.1

The law applicable to Conformity Assessment of PPE is Regulation (EU) 2016/425 and the Directive dated December 13, 2017 of the Ministry of Economic Development (MISE).

RINA is covered by a liability insurance policy for the described activities for the risks derived from the EU-type examination activity.

For the application and homogeneous interpretation of the PPE Regulation, RINA uses the Shared Opinions issued by the Forum of Notified Bodies.

CHAPTER 5 – ISSUE OF CERTIFICATES

5.1

The Organisations that wish to obtain the above certification for personal protection equipment to be placed on the market must send a specific request for offer, by fax, mail or e-mail, in compliance with the applicable requirements set forth in the Regulation, with all information required to prepare the service proposal, such as:

- a) name and address of the manufacturer or his authorized representative, if the application is submitted by the latter;
- b) description of the personal protection device;
- c) Category of the personal protection device;
- d) in case of production surveillance procedure as per Module D, any quality system certified in accordance with the ISO9001 standards and the number of workers (employees, collaborators, subcontractors) in order to define the audit duration;
- e) any standards used for the design, manufacture and control of the specific personal protection equipment.

RINA performs a preliminary check to verify whether the supplied information is sufficient to prepare a service proposal and may ask for further details, if necessary, also with reference to the requirements of the annexes to these Rules. According to this information RINA prepares a service proposal which will be sent together with these Rules and the applicable Specifications, the 'Application for PPE Conformity Assessment' form and the 'Order' form. The application shall be provided with a written declaration stating that the same application has not been submitted to any other notified body.

5.2

Upon reception of the 'Application for PPE Conformity Assessment' form and of the 'Order'

form, duly filled in for acceptance of the issued service proposal, RINA will have 10 working days to enter any comments to these proposals or reject them; if no action is carried out within this term, the request will be considered automatically accepted, therefore any RINA interventions which are carried out in accordance with these Rules will be deemed to be contractually formalized.

The 'Application for PPE Conformity Assessment' form and the 'Order' form, duly filled in by the Organisation, and the relevant acceptance by RINA contractually formalize RINA's interventions carried out in accordance with these Rules.

RINA requests the documents specified in the annexes to these Rules, for examination purposes.

RINA will inform the Organisation of the file manager's name and then the file manager will provide the name(s) of the technician(s) who will carry out the audits to the works; the Organisation can object the appointment of these auditors by justifying the reasons for the objections.

5.3

In case of production surveillance procedure as per Module D, RINA will carry out an audit to the Organisation after communicating the names of the audit team members who must check the correct application of all applicable procedures relating to design, manufacturing and control of the personal protection equipment mentioned in the application for assessment.

The Organisation can object the appointment of these auditors by justifying the reasons for the objections.

The assessment visit will consist of:

- an initial meeting with the Organisation to agree upon the auditing modalities;
- examination of the technical documents relating to the PPE (as an alternative, this examination can be preliminarily carried out; for the calculation of both back office times and duration of stage 1 and stage 2 audits reference is made to RINA certification table of quality management systems);
- a visit to the offices, the manufacturing site(s) and, where necessary, the raw material storage/withdrawal site(s), as well as the laboratory(ies) aiming to verify conformity of

the factory production control system with the reference applicable standards;

- a final meeting to explain the outcome of the audit.

RINA's audit team verifies that the Organisation's QMS is adequate to meet all applicable essential safety requirements set forth in annex II of the PPE Regulation; in the presence of any deficiencies or discrepancies with respect to the information present on the system documents, the audit team can raise one or more non-conformities.

During the audit the Organisation must demonstrate, not only that it has all the applicable reference standards but also that the system has been fully operating from at least three months and that this system and the relevant documented procedures are effectively implemented.

To this aim, also during periodic surveillance audits (as specified below), RINA technicians must freely access the production sites, the personnel and the documentation and must have the necessary assistance by the personnel in charge of the audit.

5.4

At the end of the assessment visit an Audit Report is handed to the Organisation; this audit report contains any non-conformities and recommendations raised by the auditing team.

The Organisation can express its reservations or objections, in relation to the findings raised by RINA auditors, in an appropriate space of the audit report.

The contents of this audit report are subsequently confirmed by RINA by a written communication.

In the absence of any written communication by RINA, the audit report is deemed to be confirmed after three working days from its delivery to the Organisation.

The Organisation, after analysing the causes for any non-conformities entered in the above audit report, must propose, within the date indicated in the same audit report, the required corrective actions and the times foreseen for their implementation.

The acceptance of these proposals and the times foreseen for their implementation is communicated by RINA to the Organisation in writing.

In the presence of any A-type findings (see next paragraph) the certification process is suspended; in the presence of other findings which, due to their number, in the audit team's opinion can prejudice the correct operation of the system, the certification process is suspended.

In these cases, within three months, RINA can perform a supplementary audit aimed at verifying the correct application of the proposed corrective actions; if this check is successfully performed the certification process can be resumed.

If the above deadline is exceeded, the Organisation's QMS is totally re-examined within six months from the date of the finding.

If six months elapse without a positive conclusion of the assessment, RINA can close the certification file, charging the time and expenses incurred until then. In these cases the Organisation that wishes to continue with RINA certification must submit a new application and restart the certification procedure.

In specific cases RINA can decide to change the above time limits if requested by the Organisation with adequate reasons.

The client undertakes to ensure that production sites can be freely accessed by ACCREDIA personnel and/or the competent authority for any type of visit, where required, acting as observers.

5.5

The findings relevant to the certification scope can be subdivided into the following types:

(a) A-type findings (major non-conformities):

- when one or more of the requirements of the reference standards are totally disregarded;
- a situation that may cause the delivery of a product that is not compliant with the regulations applicable in the Member State where the product will be placed on the market;
- the non-observance of one or more requirements of these Rules;
- a condition that may cause a serious deficiency of the QMS or reduce its capacity to ensure product control.

(b) B-type findings (secondary deficiencies or minor non-conformities):

- a condition that, in RINA auditing team's opinion, based on their experience, cannot cause a serious deficiency of the QMS and does not reduce its capacity to ensure product control.
- (c) C-type findings (recommendations, observations):
- suggestions to improve the system, which are not directly related to the provisions of the reference standards applicable to the product.

5.6

The inspection activities foreseen for personal protection equipment are carried out in the presence of RINA inspectors, according to the requirements of the applicable assessment procedures described in the annexes to these Rules.

Tests are carried out by RINA's Test Laboratory, at the same laboratory, at laboratories belonging to applicant Organisations or at any laboratories belong to third parties.

An assessment of the laboratory by RINA is necessary to verify that the laboratory has and/or maintains the personnel competences, infrastructures and equipment suitable to ensure metrologically reportable results complying with test specifications.

For instance, the accreditation of a laboratory for the specific test by Accredia or by a foreign body signatory of the ILAC (MRA) mutual recognition agreement is the evidence of the required competences, infrastructures and equipment.

With regard to laboratories other than RINA's Test Laboratory, such as those belonging to applicant Organisations, the presence of a RINA technician is mandatory to safeguard confidentiality, impartiality and independence of judgment.

5.7

If all examinations and tests set out in the annexes to these Rules and specified in the service proposal sent to the Organisation and accepted by it are successfully carried out, the file manager will issue the file complete with all the documentation to a RINA competent and independent technician for completeness check. Following the successful result of this check and the approval of the relevant

certification proposal, RINA will issue the Certificate foreseen by the applied procedure.

In case of negative result, RINA will inform the Organisation about this result and will agree upon any re-assessment with the Organisation.

5.8 – STORAGE OF SAMPLES

The examined samples will be stored for at least three months from the date of issue of the certificate.

At the end of this period, RINA will deliver the marked samples (with the file number and date) and any expenses will be charged to the client.

With regard to PPE belonging to the third category, RINA reserves to keep at least one sample in its store.

The Manufacturer undertakes to keep the received sample intact for at least 10 years from its placing on the market.

RINA performs surveillance audits on the PPE storage modalities adopted by the certificate holder so as to ensure conformity of the PPE.

CHAPTER 6 – CERTIFICATION VALIDITY

The EU-type Examination Certificate as per Module B will be valid for five years and can be renewed at its expiry date.

The EU Conformity Certificate of the finished product as per Module C2 is valid for one year.

The Certificate of Conformity to type based on Quality Assurance of the production process of the finished product as per Module D is valid for three years and its validity is dependent on the successful outcome of surveillance audits.

CHAPTER 7 – SUSPENSION, REINSTATEMENT AND REVOCATION OF CERTIFICATES

7.1

The validity of a Certificate can be suspended in accordance with the provisions of the "GENERAL TERMS AND CONDITIONS FOR THE CERTIFICATION OF SYSTEMS, PRODUCTS AND PERSONNEL" and in the specific cases listed here below:

- if the Organisation does not allow the planned audits to be carried out according to the required schedule;

- if, within the QMS, any non-conformities are found that are not solved within the times established by RINA;
- if the Organisation did not comply with the terms established for the communication of the corrective actions, as a result of non-conformities/observations written in the audit report;
- if the Organisation has made any significant changes to its Sites(s) or moved to another site(s) without informing RINA;
- if the Organisation has made any significant changes to its QMS that have not been accepted by RINA;
- in the presence of important changes to the Organisation that are not reported to RINA;
- in case of rejection of or obstacle to the participation in the audits of any observers of an Accreditation Body;
- in the presence of evidences that the QMS does not ensure compliance with the laws and regulations currently in force and applicable to the activities and/or the site(s);
- in the presence of any justified and serious complaints received by RINA.

Furthermore the Organisation can ask RINA, by justifying the reasons, for suspension of its certification for a period of time that is generally not greater than six months and, in any case, not exceeding the expiry date of the certificate.

Suspension is notified in writing, specifying the certificate reinstatement conditions and the term within which the required actions must be taken.

Suspension of certificate validity can be made publicly known by RINA.

7.2

A certificate can be reinstated only following verification that the deficiencies which caused said suspension have been removed by an audit to the product and the Organisation aimed at ensuring that the product and the Organisation comply with all the requirements of the reference standard.

This reinstatement is notified in writing to the Organisation and made publicly known by RINA if this suspension was made public.

7.3

Non-compliance of the conditions specified under point 7.2 above within the specified term causes the Certificate to be revoked.

The decision on Certificate revocation can be taken in accordance with the "GENERAL TERMS AND CONDITIONS FOR THE CERTIFICATION OF SYSTEMS, PRODUCTS AND PERSONNEL" and in the following specific cases:

- in the presence of any conditions, like those mentioned under point 7.1 for suspension, that are judged to be particularly serious;
- if the Organisation suspends its activities or services which are the object of the certified QMS and/or the conformity assessment of PPE for a period of time greater than six months;
- if the Organisation does not accept the new economic conditions established by RINA for any contract amendment;
- for any other serious reason, according to RINA's judgement, like for example, but not limited to, the proven inability of the system to pursue its own objectives relating to the compliance with legal or contractual restrictions or to product safety.

If the Conformity Certificate is revoked, RINA will:

- a. send a written notice to the Organisation providing it with detailed reasons for the decision of this revocation and informing it of the possibility to appeal against this decision;
- b. if the appeal is not successful, directly inform the notifying authorities (the Ministry of Economic Development and the Ministry of Labour and Social Policy), providing details of revoked certificates;
- c. inform the Technical Secretariat of the group of European Notified Bodies for personal protective equipment of the data relating to the revoked certificate.

An Organisation which, after revocation, intends to be certified again, cannot submit an application for the same PPE and any subsequent application (after amendments) will follow the entire procedure set out in these Rules.

7.4

In case of suspension or revocation of its certificates, the Organisation cannot market the products relating to suspended or revoked certificates that are stored in the warehouse or being delivered.

CHAPTER 8 – LIST OF ISSUED CERTIFICATES

8.1

RINA periodically makes available the list of issued certificates to the Ministry of the Economic Development.

This list can be published by RINA on its website.

This list contains:

- the Organisation's name and address;
- the Certificate number;
- the description of the certified PPE;
- the issue date of the Certificate;
- the expiry date of the Certificate

The above information can also be provided by RINA to:

- the Accreditation Bodies, in relation to the status and type of accreditation,
- any Federations of Certification Bodies to which RINA belongs,

to be entered in the relevant databases.

As a general rule, within one month from the date of the notice, RINA will update the certificate status.

CHAPTER 11 – CONTRACTUAL CONDITIONS

11.1

With regard to contractual conditions, the provisions of the following RINA document apply: "General Terms and Conditions for the certification of Systems, Products and Personnel", in its current edition; this document can be found in www.rina.org website.

CHAPTER 9 – CERTIFICATE TRANSFER

9.1

If the company's name changes, the Organisation must inform RINA of the changes made, by sending the following documents:

- a copy of the new Chamber of Commerce registration certificate or an equivalent document,
- a copy of the notarial act certifying this change.

After performing all necessary checks, RINA will issue a new certificate and make the previous one not valid.

CHAPTER 10 – RENUNCIATION OF CERTIFICATES

10.1

The certified Organisation can send a formal renunciation notice to RINA, before the certificate expires, including when the Organisation itself does not intend to or cannot meet the new requirements set out by RINA.

Upon reception of the above notice, RINA starts a procedure to make the certificate status not valid.

Annex 1 – Module B – EU-Type Examination

MODULE B (EU-Type Examination)

Within the context of this procedure, RINA verifies and declares that a specimen, representative of the production envisaged, meets the provisions of this Regulation.

The manufacturer or his authorized representative (if specified in the mandate – hereinafter simply referred to as “manufacturer”) must lodge an application for EU-Type examination in accordance with the procedure described in Module B of the PPE Regulation enclosing, for each ‘type’, the following technical documents relating to PPE manufacture which includes:

- a mandate if the application is submitted by the authorized representative instead of the manufacturer;
- a thorough description of the PPE and its use;
- a declaration of the risks against which the PPE is intended to protect;
- a list of essential health and safety requirements applicable to the PPE;
- design and manufacturing drawings and diagrams of the PPE and relevant components, subassemblies and circuits;
- explanations required to understand the above drawings and the operation of the PPE;
- reference to any harmonised standards that have been applied during design and manufacturing of the PPE. If harmonised standards have been partially applied, documentation describing which parts of the standards have been applied;
- if the harmonised standards have not been applied or have been partially applied, a description of the other technical specifications adopted to meet the applicable essential health and safety requirements;
- results of design calculations, inspections and examinations performed to verify compliance of the PPE with the applicable essential health and safety requirements;
- reports on tests carried out on prototypes, to meet the essential health and safety requirements and , if it is the case, to determine the relevant protection class;
- description of the means used by the manufacturer when manufacturing the PPE to ensure compliance of the manufactured PPE with the design specifications;
- a copy of the manufacturer's instructions and information referred to in Annex II, p. 1.4 of Regulation (EU) 2016/425;
- with regard to any PPE manufactured as single units to adapt to and individual user, all instructions required to manufacture said PPE according to the approved basic model;
- with regard to mass-produced PPE in which each item is manufactured to adapt to an individual user, a description of the measures to be taken by the manufacturer during the assembly and production process to ensure that each piece of PPE complies with the approved type and with the applicable essential health and safety requirements

The technical documentation must be integrated with the PPE Manufacturer's information note, written at least in the language(s) of the member state(s) of destination, containing the following information, as far as applicable:

- a) name of address of the Manufacturer or his authorized representative in the European Community;
- b) storage, use, cleaning, maintenance, revision and disinfection instructions. Any cleaning, maintenance or disinfection products recommended by the Manufacturer, when used, can have no harmful effect for the PPE or its user;
- c) the accessories that can be used with the PPE and the characteristics of appropriate spare parts and allowed connections;
- d) the protection classes appropriate to different levels of risk and the corresponding limits of use;
- e) the expiry date of the PPE or of some of its components;
- f) the type of packaging suitable for transport of the PPE;
- g) the meaning of the indications affixed on the PPE;
- h) maximum design depth;
- i) other safety devices required, with reference to their risk of use;
- j) temperature conditions;

Annex 1 – Module B – EU-Type Examination

- k) visibility;
- l) types of possible activities;
- m) checks to be carried out before use;
- n) dressing and undressing modalities;
- o) other recommendations at the discretion of the manufacturer.

Furthermore the manufacturer must make available one or more specimens representative of the production, hereinafter referred to as "type". The same type may cover one or more variations of PPE provided that differences between variations do not affect the safety level.

As a result of this, RINA:

- examines the technical documentation to verify compliance of the technical project, sends any comments, performs appropriate checks;
- with regard to mass-produced PPE in which each item is manufactured to adapt to an individual user, examines the description of the measures in order to verify their adequacy;
- with regard to PPE manufactured as single units to adapt to an individual user, examines the PPE manufacturing instructions according to the approved basic model, to verify its compliance;
- checks that the samples have been manufactured in compliance with the submitted technical documents, highlighting the elements designed in conformity with both the harmonized standards and other reference standards;
- performs appropriate checks and tests or have them performed to check that, if the manufacturer has chosen to apply the solutions as per the applicable harmonized standards, these solutions have been correctly applied and listed in Annex II of Regulation (EU) 2016/425;
- performs appropriate checks and tests or have them performed in order to verify whether, in case no solutions as per the applicable harmonized standards have been applied, the solutions adopted by the manufacturer, including those mentioned in other applied technical specifications, meet the applicable essential health and safety requirements and have been applied;
- issues a Test Report which lists the above activities and relevant results.

If the laboratory where examinations and tests are carried out is different from RINA's laboratory, RINA will inform the manufacturer of which laboratory will be used asking him for his prior approval.

If the outcome of the checks and tests is positive, RINA provides the manufacturer with an EU-type Examination Certificate, valid for 5 years, containing the manufacturer's name and address and the data required to identify the approved type. The certificate and its annexes provide information about the tests carried out as well as the descriptions and list of drawings required to identify the certified PPE.

If the manufacturer, which has received an EU-type examination certificate from RINA, makes any changes to the approved product that may affect conformity with the essential applicable requirements of the prescribed methods of use, these changes must be reported to RINA and shall be further checked and approved. This new approval consists of a new issue of the EU-type examination Certificate.

If the type does not meet the essential health and safety requirements, RINA refuses to issue an EU-type Examination Certificate and informs the Manufacturer, stating detailed reasons for this refusal.

RINA will inform of this refusal the notifying authorities and the other notified bodies. The applicant cannot submit a new application for certification unless any changes to the PPE necessary to meet the prescribed requirements have been made.

Revision of the EU-type Examination Certificate

RINA shall keep itself apprised of any changes of the generally acknowledged state of the art and, if it determines that such changes require further investigations, informs the manufacturer requesting to revise the EU-type examination certificate.

If the manufacturer, with a valid EU-type examination certificate issued by RINA, makes any changes to the approved product and the relevant technical documentation which may affect compliance with the applicable essential requirements or the prescribed conditions for use, these changes must be reported to RINA and shall be further assessed and approved.

The manufacturer requests RINA to revise the EU-type examination certificate under the conditions described in the previous paragraph and following developments in the state of the art to ensure that the PPE still satisfies the essential health and safety requirements. In the light of any changes made and developments in the state of the art, RINA will

Annex 1 – Module B – EU-Type Examination

perform the tests required to ensure that the approved type still meets the applicable essential health and safety requirements.

This application for revision, provided with all associated documents, must be received within six months from the expiry date of the EU-type examination certificate to enable RINA to perform all necessary tests within the expiry date of the certificate. If, following these tests, the approved type still meets the applicable health and safety requirements, RINA re-issues the EU-type examination certificate, otherwise revokes it and informs the manufacturer.

Renewal of the EU-type Examination Certificate

The manufacturer shall submit an application for certificate renewal not more than twelve months and not later than six months before the expiry date of the so as to allow RINA to perform the necessary checks during the validity of the certificate.

RINA renews the EU-type Examination Certificate with 5 year validity in the presence of positive outcome of the tests carried out relating to any changes made or developments in the state of the art to ensure that the approved type still meets the essential health and safety requirements.

When the application for renewal or the associated documentation is submitted after the six-month deadline before the expiry date of the certificate, RINA will not ensure that the certificate will be renewed before its expiry date. An expired certificate is no longer valid and the manufacturer cannot place the relevant PPE on the market. If the relevant checks have positive outcomes, the renewed certificate will be valid for 5 years starting from the expiry date of the previous certificate.

If no other changes or further investigations are made to adapt to the state of the art, RINA will observe a simplified renewal procedure which requires the following information/documents:

- name and address of the manufacturer and details of the EU-type approval certificate in question;
- a declaration stating that no changes have been made to either the approved type, including materials, subcomponents or subassemblies, nor the applicable harmonized standards or applied technical specifications;
- a declaration stating that no developments in the state of the art have occurred;
- if not already supplied to RINA, copies of current drawings and images of the product, marks and information made available by the manufacturer and
- for category-III products, if not already available to RINA, information about the outcomes of any official product tests carried out at random intervals (valid Module C2) or the outcomes of audits to its quality system (valid Module D).

Following the confirmation that no changes have been made to the approved type and that no developments in the state of the art have occurred, RINA renews the certificate with the simplified procedure and the validity starts from the expiry date of the previous certificate.

The costs relating to this renewal are proportionate to the administrative burdens of the simplified procedure.

Communication to the interested Parties

RINA shall inform the notifying authorities about any issued or withdrawn EU-type examination certificates by publicising them in RINA website. On request, RINA makes available the list of issued, refused, revoked or suspended certificates to the above authorities.

RINA informs the other notified bodies about any suspended or withdrawn EU-type examination certificates by publicising them in RINA website. On request, RINA makes available the list of issued certificates to the above Bodies.

Annex 2 – Module C2 – Product verification

MODULE C2 (Product Verification)

Within the context of this procedure, the manufacturer verifies and declares that the PPE subject to surveillance audits by RINA and described in paragraph "Product verification" is in conformity with the type as described in the EU Type-Examination Certificate and satisfies the essential safety requirements which apply to it.

Furthermore the manufacturer must take all measures required to ensure that the manufacturing process guarantees homogeneity of production and the PPE compliance with the type as described in the above Certificates.

The manufacturer must affix the CE marking to each personal protective device and draw up a Declaration of Conformity.

The manufacturer must lodge an application for CE marking authorization in accordance with the procedure described in Module C2 of the PPE Regulation and must include the following documents for each type of PPE that it intends to mark:

- a) a general description of the personal protective equipment;
- b) a copy of the CE examination Certificate issued by a Notified Body with all relating technical documentation.
- c) a declaration relating to the batches manufactured in the year preceding the submission of the application and information about the place where taking of the specimens to be tested will be carried out.

RINA examines the submitted documentation, according to the received information, and agrees upon a sampling plan with the manufacturer.

The sample examined by RINA shall comply at least with the requirements laid down in ISO 2859-1 (Sampling Procedures for Inspection by Attributes), inspection level S-2. In particular, for each homogeneous production batch, as defined by the manufacturer:

- 1) for batches with up to 25 specimens, a sample size "code A";
- 2) for batches from 26 to 150 specimens, a sample size "code B";
- 3) for batches from 151 to 1200 specimens, a sample size "code C";
- 4) for batches from 1201 to 35000 specimens, a sample size "code D";
- 5) for batches over 35000 specimens, a sample size "code E".

A homogeneous production batch can be defined on the basis of the production site or inhomogeneities of parts or subcomponents or the different assembly of these parts. The homogeneity of the batch and the quantity and number of batches are declared by the manufacturer and a RINA technician shall verify the functionality of individual products belonging to the batch.

The number of specimens to be tested depends on the type of inspection (reduced, normal or enhanced), as suggested by the manufacturer as a function of the production control level he declared. Before the activity is started, RINA re-examines the received information about homogeneous production batches and production control to confirm the sampling plan.

The manufacturer shall make available a sufficient number of specimens to make up a sample for each homogeneous batch in order to examine the specimens. This sampling shall be carried out within the ninth month from the date of issue of the currently-valid Module C2.

RINA checks compliance of the PPE with the requirements of the Directive through examinations and tests on the stored specimens, as described in the following paragraph.

Product verification

A RINA technician examines the batches manufactured as agreed, the specimens taken from these batches which have been stored in the selected site (e.g. production line, warehouse, shop) with methods of sampling aimed at verifying homogeneity of production.

To check the homogeneity of the batch, RINA technician shall take into account any collected evidences on production control and supplies, tests on any stored samples, the complexity and critical aspects of parts and components during the manufacturing phase.

After checking the availability of specimens as declared in the sampling plan, RINA technician checks them to verify compliance of the samples with the specimen examined in the EU-type Examination Certificate. These tests must be

Annex 2 – Module C2 – Product verification

conducted in accordance with the provisions of the applicable Harmonized Standards or, failing these, in accordance with the agreements between the Manufacturer and RINA signed upon submission and approval of the application.

If the outcome of these tests is positive, RINA will issue a CE Conformity Certificate of the finished product with one-year validity. The renewal of this certificate can be carried out only within the expiry date.

Whenever test samples used for the type test have been collected from the production line (i.e. they are not prototypes), the tests carried out for the issue of the EU-type Examination Certificate can also be deemed to be valid as a first test on production provided that the existence of a contract relating to surveillance has been verified.

In this case the CE Conformity Certificate of the finished product is issued together with the EU-type examination certificate.

Issue of and application for certificate renewal

Within nine months from the issue of Module C2 certificate, the manufacturer shall inform RINA of the products mentioned in the certificate according to the decided sampling and place and agree on the audit by a RINA technician who will check the product in compliance with the requirements laid down in paragraph "Product verification".

If production is absent in that period, the manufacturer shall inform RINA in writing; in this case the Module C2 certificate will remain valid until the manufacturer informs that production is restarted and, in any case, not after its natural expiry date.

If production is absent until the expiry of Module C2 certificate, RINA will suspend the Module C2 certificate and informs the manufacturer of this suspension.

If production is restarted after the expiry date of Module C2 certificate, the manufacturer shall inform RINA in order to proceed with product verification for the subsequent reinstatement of said certificate.

In any case, when tests relating to product verifications are successfully completed, a new Module C2 certificate is issued if the application for renewal has been submitted within three months from the expiry date of the certificate. The validity of the new certificate will start from either the expiry date of the previous certificate if it is still valid upon product verification or the date of the same product verification and shall be valid for one year starting from the expiry date of the previous valid certificate.

After nine months, if the manufacturer is not willing to out this sampling and the audit, RINA will suspend the Module C2 certificate and inform the manufacturer of this suspension.

RINA will also inform the manufacturer of the conditions to restore the certificate (sampling is required) and the term within which they must be implemented (expiry date of Module C2).

During the suspension period, the manufacturer cannot use RINA certificate (certificate number, identification number of RINA Notified Body, etc.) on the manufacturer's declaration of conformity in relation to the CE marking of the product in question for the placing on the market.

RINA reserves the right to conduct unannounced audits with a higher frequency than scheduled according to the results of the tests, the quantity of produced batches (different from the one that was initially declared by the manufacturer) and information coming from the market.

Negative results of product verifications or lack of available specimens by the manufacturer

If the tests do not have positive results or if the manufacturer does not make available any specimens to be used for product verification (even partial), three months before the expiry date of the Module C2 certificate, RINA will suspend it as long as the corrective actions agreed upon with the manufacturer have been implemented. On the basis of the critical aspects or defects found, RINA will repeat all or part of the tests that are either failed or not carried out, as requested.

In the most serious cases, or whenever the Manufacturer cannot ensure homogeneous production, RINA will suspend certification and inform the notifying authorities, so that the PPE found to be non compliant is withdrawn from the European market.

Annex 3 – Module D – Production quality assurance

MODULE D (Production Quality Assurance)

Within the context of this procedure, the manufacturer must use an approved Quality System for production, final inspection and tests on the finished product, as specified in "Quality System" and be subject to surveillance by RINA as specified in paragraph "Surveillance".

The manufacturer establishes and declares that the personal protective equipment is in conformity with the type as described in the EU Type-Examination Certificate and satisfies the essential safety requirements which apply to it.

The manufacturer must affix the CE marking to each personal protective device, indicating RINA identification number and draw up a Declaration of Conformity.

Quality system

The manufacturer must lodge an application for assessment of its Quality System for the products concerned, in accordance with the procedure described in Module D of the PPE Regulation and must include the following documents:

- a) a general description of the personal protective equipment;
- b) a copy of the quality documentation relevant for the purposes of the PPE Regulation (this documentation is listed below and alternatively may be acquired and examined by RINA during the audit);
- c) a copy of the EU Type-Examination Certificate and the corresponding technical documentation;
- d) a copy of the ISO9001 certificate, if the QMS is certified, or a copy of the QMS documents (if not certified), including the elements required by Regulation 2016/425.

All the criteria, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This Quality System documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records.

The Quality System documentation must contain in particular an adequate description of:

- a) quality objectives, organisational structure and management responsibilities with regard to the quality of the personal protective equipment;
- b) manufacturing processes, systematic operations and quality control and assurance techniques;
- c) examinations and tests carried out before, during and after manufacture, and the frequency with which they are intended to be carried out;
- d) quality documents, such as inspection reports and test and calibration data;
- e) means of monitoring the achievement of the required quality and the effective operation of the Quality System.

The Quality System must guarantee conformity of the personal protective equipment with the type as described in the EU Type-Examination Certificate and with the essential safety requirements which apply to it. The Applicant's QMS is subject to examination and approval by the N.B. in accordance with the criteria described in this Regulation and in the "Rules for the Certification of Quality Management Systems" document available in the www.rina.org website, to decide whether it meets the PPE Regulation requirements. This system shall also be subject to surveillance by RINA.

When the manufacturer deems that the documentation of its QMS is in line with the PPE Regulation, it can request RINA to carry out the audit.

During the first certification audit, RINA will assess the fundamental issues of the Quality System in relation to the requirements of the PPE Regulation, using the reference checklist, where appropriate; it will also assess the Quality System as a whole if this has been certified by a body other than RINA.

At the end of the audit, RINA will issue a copy of the audit report.

The audit team must have the competence required to assess both the QMS and the product and must include at least one technical expert for assessing the personal protective equipment concerned. The assessment audit will include an inspection visit to the manufacturer's plants.

Annex 3 – Module D – Production quality assurance

If the outcome of assessment activities is positive, in other words if no serious (type B) findings or simple recommendations have been raised, RINA issues a Certificate of Conformity to type based on Quality Assurance of the production process. RINA will carry out another visit to verify that the changes agreed during the audit have been implemented within the agreed deadline.

If serious findings are raised or if the number of non-serious findings prejudices compliance with the essential safety requirements, RINA will carry out an audit within the deadline written in the audit report (which allows the manufacturer to take action on its Quality System, integrating the changes required) and will not issue any Certificate of Conformity.

After the second audit is carried out, if the result is positive or falls within the above limits, RINA will issue the Certificate of Conformity to type based on Quality Assurance of the production process.

The Certificate of Conformity to type based on Quality Assurance of the production process is valid for three years.

If even the second audit is not successful, RINA will inform the other Notified Bodies that it has denied certification of conformity.

The manufacturer undertakes to fulfil the obligations arising out of the Quality System as approved and to ensure that it remains satisfactory and efficient.

The manufacturer, or his authorized representative established within the Community, must inform the Notified Body that has approved the Quality System of any intended change to the Quality System.

The Notified Body must assess the proposed changes and decide whether the amended Quality System will still satisfy the requirements referred to above or whether a second audit is required.

The Notified Body must inform the manufacturer of its decision. This communication must contain the conclusions of the examination and detailed reasons about the decision.

Surveillance

The purpose of surveillance is to make sure that the manufacturer fulfils all the obligations arising out of the approved Quality System.

RINA carries out the Quality System surveillance by implementing a time schedule that includes a maintenance audit at the end of the first year, a maintenance audit at the end of the second year and a renewal audit at the end of the third year; these audits will be conducted by product specialists and ISO9001 system auditors.

The manufacturer shall submit an application for the renewal of his Module D certificate at least six months before the expiry date of the certification period (three years). If the application for renewal is submitted after this date, RINA does not ensure the validity of Module D beyond the natural expiry date.

RINA reserves the right to carry out further occasional visits, even without notice.

During each of the maintenance audits, RINA will carry out a complete review of the company MS or apply a review programme that leads to a thorough reassessment of the company MS during the two audits.

During the scheduled audits, the manufacturer shall provide RINA with the following documents:

- documents relating to the Quality System (quality plans relevant to the certified products or equivalent documents)
- internal inspection reports
- calibration certificates of test equipment
- non-conformity reports issued in production and relevant resolutions;
- Declaration of conformity.

If possible, during the audits, the tests performed by the manufacturer during the various production stages and for acceptance should be submitted, in order to verify compliance with the requirements.

RINA also establishes that the CE marking is correctly affixed.

When the result of these activities is positive, RINA issues a final assessment report.

Annex 3 – Module D – Production quality assurance

When the certificate validity expires, the manufacturer must send another application for assessment of its Quality System and RINA will make a thorough review of the whole company Quality System.

The manufacturer must keep the documents listed below, for a period of ten years from the last manufacturing date of the personal protective equipment, at the disposal of the national authorities:

- the quality system documentation referred to in point c) of the 'Quality System' paragraph;
- any changes to its quality system;
- any decisions and reports issued by RINA relating to the approval of the company Quality System, any changes made and any scheduled and unexpected audits carried out.



Annex 4 – Facsimile of the Declaration of Conformity

FACSIMILE OF THE DECLARATION OF CONFORMITY

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

Three horizontal lines for text entry.

Declares that the new PPE described hereinafter: (2)

Four horizontal lines for text entry.

is in conformity with the provisions of Regulation (EU) 2016/425 and is identical to the PPE which is the subject of EU-type Examination Certificate no. _____ issued by: (3)

Three horizontal lines for text entry.

the

One horizontal line for text entry.

is subject to the procedure set out in Module C2 or Module D of Regulation (EU) 2016/425 under the supervision of the Notified Body: (4)

Three horizontal lines for text entry.

Place and date: _____ on _____

Signature (5)

Horizontal line for signature.

- (1) Company name and address; in the presence of an authorised representative, state also the name and address of the Manufacturer
(2) Description of the PPE (trademark, type, serial number, etc.)
(3) Name and address of the appointed Notified Body
(4) Delete as appropriate
(5) Name and position of the person empowered to sign on behalf of the Manufacturer or its authorised representative



Annex 5 – Facsimile of the Declaration of the Certificate Owner

Declaration of Certificate Owner

.....

(Name and logo of the Owner)

Date

To

RINA Services SPA
Via Corsica, 12
GENOVA
ITALY

Subject: Issue of secondary product certification

.....

(identification of type and brand name)

We hereby confirm that we intend to supply the above product, as described in EU-type examination certificate

No.....

to the following Company:

.....

that will supply this product with the following brand name:

.....

The Declaration of Identity of said Company is enclosed herein.

CONDITIONS OF VALIDITY

Furthermore we undertake to make no change to the finished product, and timely inform you if the contract with the above Organisation is cancelled.

Timely inform the N.B. in the presence of accidents.

Timely inform the N.B. which is responsible for the product surveillance in accordance with Modules C2 or D, if appropriate.

Stamp and signature of an authorised person



Annex 6 – Facsimile of the Declaration of Identity

Declaration of Identity

.....

(Name and logo of the Company)

Date

To

RINA RINA Services SPA
Via Corsica, 12
GENOVA
ITALY

Subject: EU-type product certification

.....

(identification of type and brand name that the Company intends to use to market the product)

We hereby inform you that we intend to market the above product and that it is supplied to us only by the manufacturing company:

.....

(name of Owner)

This product is identical to the one manufactured by the manufacturing company with the following identification of type:

.....

and with the brand name:

.....as described in EU-type Examination Certificate

no.....

CONDITIONS OF VALIDITY

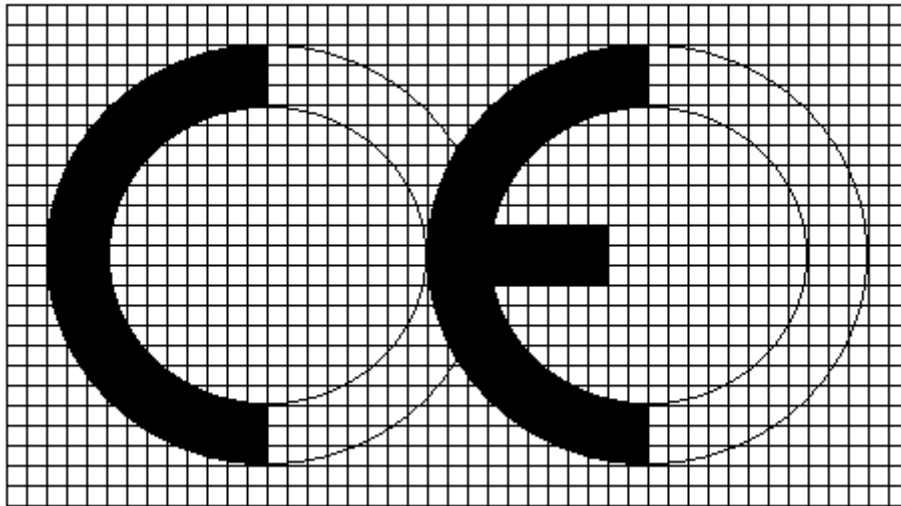
Furthermore we undertake to make no change to the finished product, and timely inform you if the contract with the above Organisation is cancelled.
Timely inform the N.B. in the presence of accidents.
Timely inform the N.B. which is responsible for the product surveillance in accordance with Modules C2 or D, if appropriate.

Stamp and signature of an authorised person

Annex 7 – CE Marking

The CE conformity marking consists of the CE letters which make up the graphic symbol shown in Figure 1.

Figure 1



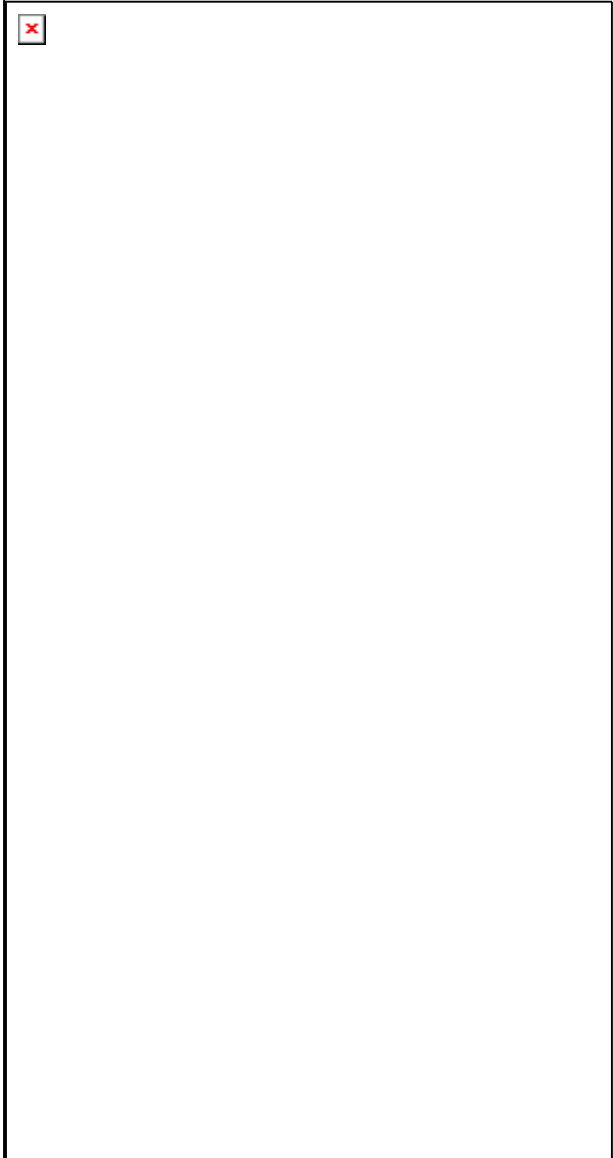
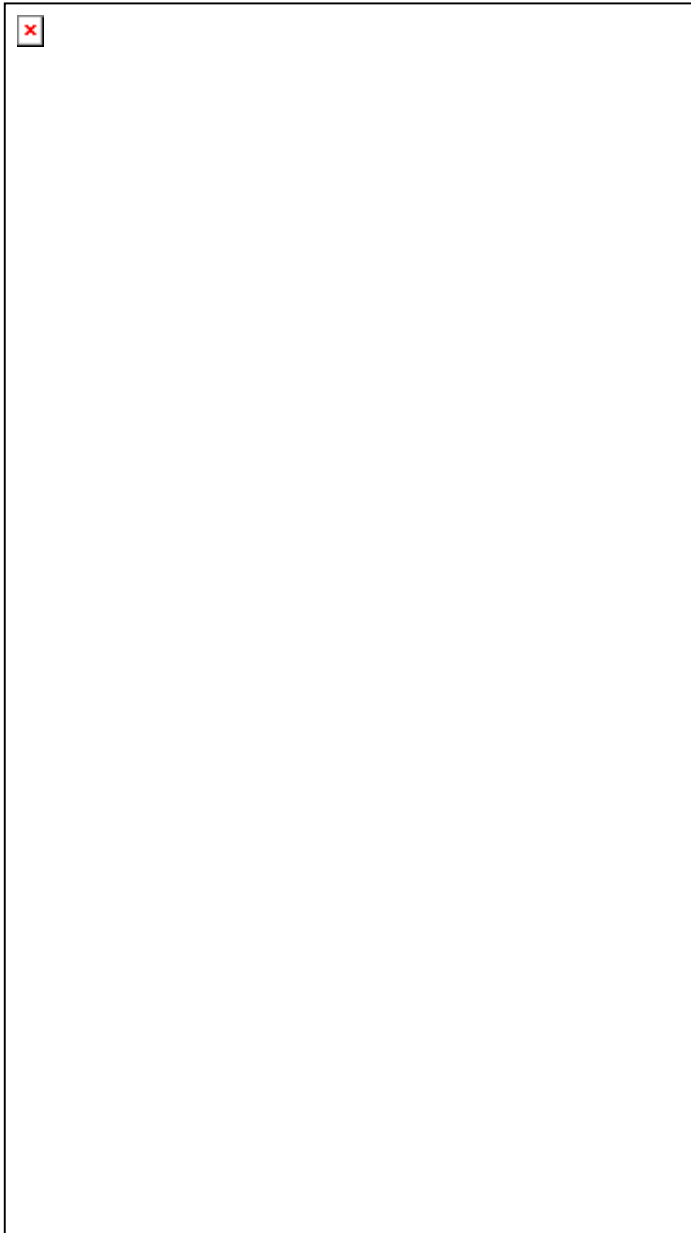
If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.

The various elements of the CE marking substantially have the same vertical dimension which cannot be lower than 5 mm. This minimum dimension may be waived for small-scale objects.

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

The CE marking can be affixed in any position provided that it cannot be confused with any other marks or inscriptions affixed by the Manufacturer.

Annex 8 – Table ISO 2859-1 “Sampling Plans”



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RINA
Via Corsica 12
16128 Genova - Italy

tel +39 010 53851
fax +39 010 5351000
web site : www.rina.org

Technical Rules