Regulations on the issuance of the Statement of Compliance in accordance with a reference standard for products similar to PPE

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Technical Regulations

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ATTACHMENTS

CAPITOLO 1. - GENERAL

1.1

This Regulation illustrates the procedures applied by RINA Services S.p.A. (hereinafter RINA) for the certification of the conformity of one or more products to a reference regulatory document based on the results of tests and inspections carried out by RINA on objects similar to PPE that do not fall into any category of PPE, but which may be parts or components of PPE.

In this type of certification, RINA does not act as a Notified Body, nor does the Testing Laboratory of RINA Services S.p.A. act as a Notified Laboratory.

1.2 Definitions

"Statement of Conformity": it is the declaration issued by RINA that certifies that a specific specimen produced by the Organization uniquely identified on the Statement complies with a standard or a specific regulatory document specified in the Statement of Conformity.

"Reference normative document": norm or standard (or part thereof) issued by international bodies in the edition in force.

"Organization": a company, operator, firm, enterprise, body or association, whether legally recognized, public or private, which has its own functions and its own administration and producer of the specimen being certified.

"Applicant": it is the Organization that requests RINA to issue the Statement of Conformity in its name; it may coincide with the manufacturer of the specimen being verified.

1.3

Access to the Statement request is open to all Organizations and is not conditioned by whether they belong to any Association or Group. For the Statement activity, RINA will apply its own tariffs in force, ensuring their fairness and uniformity of application.

RINA may legitimately refuse to accept requests for certification concerning Organizations subject, or whose production or activity is subject, to restrictive, suspensive or interdictory measures by a public authority.

If RINA does not accept a request for Statement, it will communicate the reasons to the Applicant.

The participation of observers appointed by the Organization in the tests and inspections is agreed in advance between RINA and the Organization.

1.4

RINA issues the Certification in accordance with the requirements of the UNI CEI EN ISO/IEC 17065 standard to Organizations whose product(s) have been recognized as compliant with all the requirements of the reference regulatory document.

The Certification issued by RINA is not to be confused with the Certification activity carried out as a Notified Body or as a Notified Laboratory and the specimens subject to certification have been evaluated as they were produced exclusively by the requesting Organization.

This Statement is issued upon successful completion of the tests and inspections carried out on specimens of the product itself and on the documentation that accompanies them, in accordance with the relevant regulatory document.

In relation to the reference regulatory document, the type of product or its intended use, RINA may request additional copies or detailed documents for the issuance of the Statement.

1.5

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

CAPITOLO 2. – SCOPE OF APPLICATION

2.1

This Regulation applies exclusively to the products and reference regulatory documents that the Laboratory can perform tests and inspections according to international standards are reported on the www.rina.org website.

CAPITOLO 3. – INSURANCE POLICY

3.1

RINA is covered by a Civil Liability insurance policy for the activities described for the risks derived from the Statement activity.

CAPITOLO 4. – GENERAL REQUIREMENTS FOR THE ISSUANCE OF THE STATEMENT OF CONFORMITY

4.1

Organizations wishing to obtain the Statement for one or more products in accordance with a standard or reference documents, must send by fax, post or e-mail the "Information Questionnaire" completed in all its parts, according to the applicable requirements, which contains the information necessary for the formulation of the service proposal, such as:

a) Organization Data.

b) Type of product(s) and product(s) (description, trade name, etc.).

c) Intended use.

d) Reference standard or document to which the conformity of the tested and inspected specimens must be declared.

RINA carries out a preliminary examination to verify whether the information provided is sufficient to carry out the requested service, reserving the right to request further details, if necessary, also with reference to what is reported in the annexes to these Regulations. Based on these indications, a service proposal is formulated by RINA which will be sent together with these Regulations, a specification on the number and type of specimens to be sent to the Testing Laboratory of RINA Services S.p.A. under the form 'Application and Order Confirmation for the Assessment of the Conformity of the Devices to a Reference Standard'.

This information is required to verify in advance the feasibility by the Laboratory of the related tests and inspections and the applicability of the product to the requirements described in the standard or reference document.

Any information received by the Applicant is kept confidential.

Based on this information, RINA may formulate a specific financial offer which will be sent to the Organization together with any specifications indicating the number and type of specimens to be sent to the RINA Test Laboratory.

The Applicant (hereinafter also referred to as the "Organization"), in the event of acceptance of the financial offer sent by RINA, formalizes the request for certification by sending RINA the appropriate "Request for Certification" form together with the requested copies and the associated documentation.

Upon receipt of the "Certification Request", any related attachments, copies and associated documentation, after a preliminary examination to verify their completeness, RINA sends the Organization, in writing, confirmation of acceptance of the request itself and communicates the name of the contact person for the certification file and the technician in charge of the inspections.

The Organization may object to the appointment of such technicians, justifying the reasons for doing so.

The request of the Organization, in which these Regulations are expressly referred to, and the related acceptance by RINA contractually formalize the relationship between RINA and the Organization and the applicability of these Regulations.

The contract between RINA and the Organization

savvies:

- the documentary examination referred to in Annex 1.
- checks and tests on specimens of the product(s) for which the Statement of Conformity is requested with respect to a reference document.
- upon successful completion of the above-mentioned activities, the issuance of the Certification referred to in Annex 3.
- any additional services specified in the offer.

4.2

The inspection activities of the supplied specimens and the associated documentation are carried out by RINA technicians, on the basis of the applicable requirements described in the reference regulatory document and in the manner described in the annexes to these Regulations.

The tests are carried out by the RINA Test Laboratory, at the Testing Laboratory itself, at laboratories belonging to the applicant Organization or at third-party laboratories.

The carrying out of the tests in laboratories other than the RINA Test Laboratory requires a prior

assessment of the laboratory by RINA, aimed at verifying that it has and/or maintains the skills of the staff, the infrastructures and the equipment adequate to guarantee results that can be traced metrologically and comply with the test specifications.

Prior assessment of the Laboratory is not necessary in case of a Laboratory Accredited for the specific test by ACCREDIA or in any case accredited by a Signatory Body to the MRA EA or MLA ILAC Mutual Recognition Agreements.

Carrying out the work in laboratories other than the RINA Laboratory or other than the Organization must be authorized in advance by the Organization.

The metrological traceability of the equipment of these laboratories must be ensured with instruments calibrated by LAT Centers or by bodies that have signed the ILAC Mutual Recognition (MRA) with an adequate frequency.

In the case of laboratories other than the RINA Test Laboratory, such as, for example, those belonging to the Organizations requesting the certification, the presence of the RINA Technician is mandatory to safeguard confidentiality, impartiality and independence of judgment.

Before the tests, the RINA Technician will verify all the conditions necessary for the correct execution of the tests (personnel, equipment, equipment calibration, environmental conditions, etc.).

If the adequacy of personnel, equipment or traceability of measurements is not guaranteed, such evidence is not considered valid for the purpose of issuing the Statement.

4.3

Upon successful completion of all the inspections and tests provided for in the annexes to these Regulations and specified in the offer signed by RINA and the Organization, the Practice Manager sends the file complete with all documentation to a competent and independent RINA Technician for verification of completeness. Following the successful outcome of this verification and the approval of the related Statement proposal, RINA will issue the required Statement (see Annex 3 for a FACSIMILE).

In the event of a negative outcome, RINA shall notify the Organization of this outcome which prevents the issuance of the Statement of Conformity, giving detailed reasons for this and to agree with it on the modalities for any revaluation.

4.4 – MANAGEMENT OF SPECIMENS TO BE TESTED AND INSPECTED

The customer must send a certain number of specimens to RINA for inspection and testing. The number of these specimens will be defined according to the tests/verifications to be carried out, which are reported in the specifications sent during the bidding phase.

Once examined and tested, these specimens will be kept by RINA until the relevant Statement is issued.

The specimens will then be sent back to the Customer, unless otherwise agreed (e.g. disposal).

In case of return, the shipping costs will be borne by the Organization.

4.5 – TECHNICAL DOCUMENTATION PROVIDED BY THE ORGANIZATION

Together with the request for Statement, or after it, the Organization must make available to RINA:

- Technical documentation regarding the product(s) referred to in the specification (e.g.: dimensions, materials.
- Exploded drawings, of individual components and/or of electronic diagrams and circuits (if applicable).
- Safety Data Sheets covering the product(s) and component materials for safe handling, processing and combustion.
- Copy of the Statement of registration with the Chamber of Commerce or equivalent document as evidence of the existence of the Organization and the activity carried out.

RINA may also request, at its discretion, other documents deemed important for the purposes of certifying the product's Conformity.
A copy of the examined documentation is retained by RINA for future reference for the duration of the Statement (five years).
The original documentation is still returned to the Organization after the Statement has been issued.

4.6 – VALIDITY OF THE STATEMENT

The Statement of Conformity is valid for no more than five years, renewable upon expiry, upon request.

The Statement loses all validity if:

- The Organization has changed its address, company name, name, etc.
- the Organization has made design changes of any kind to the drawings

mentioned in the Statement (dimensions, assemblies, assembly, controls, materials, etc.) or to the identifications that accompany the tests and inspections carried out on which the Statement of conformity is based.

- The international standards on which the tests or inspections mentioned in the Statement of conformity (see Annex 2) are based are no longer in force.

CAPITOLO 5. – TERMS & CONDITIONS

11.1

For the contractual conditions, the provisions contained in the RINA Standards "General Conditions of Contract for the Certification of Systems, Products and Personnel", in the current edition, which can be consulted on the www.rina.org website, apply.

The contract may be modified, subject to agreement between the parties, if the conditions based on which the initial offer was drawn up by RINA are significantly modified over time.

ANNEX 1

EXAMINATION OF DOCUMENTATION

The documentation provided by the Organisation in accordance with paragraph 4.5 is assessed by RINA on the basis of the requirements contained in the relevant regulatory document and in accordance with these Regulations.

The outcome of this examination is communicated to the Organization by sending a copy of the documentary evaluation report in which any findings found are reported and justified in detail. The Organization, after proposing to RINA corrections to the documents examined following the findings issued and, if such actions are approved by RINA, may request a further evaluation of the reissued documentation with a different revision index.

The findings that emerged during the documentary examination must be resolved by the Organization itself before the continuation of the compliance verification process. The documentation referred to in 4.4 is, in general, retained in each revision for archival use by RINA.

In the case of specific agreements with the Organization, part of the aforementioned documentation can be verified directly with the Organization itself. In this case, only the reference to the unique identification of the document will be kept by RINA.

Among the controlled documents related to the design and manufacture of the product can be:

- Product/production specifications.
- Construction drawings/production specifications
- Calculation notes.
- Fabrication/processing/preparation plans.
- Control and test plans.
- Quality plans.

EXAMINATION AND TESTING OF SPECIMENS

Copies of each product must be subjected to the tests and investigations deemed necessary in order to verify the complete compliance of the product itself with the reference regulatory document. The number and type of copies that the Organization must send to RINA are described in the specification sent following the acceptance of the offer.

Following the outcome of the inspection and tests on the specimens, RINA will issue a Test Report listing the inspections and tests to which the specimens have been subjected and their results.

Following the positive outcome of these results, the verification cycle will continue with the evaluation by the independent technician. In the event of a negative result, the evaluation is interrupted with the issuance of the Test Report only

ANNEX 2

STATEMENT OF COMPLIANCE
*N° **LABxxxxyyCS***

We state that the following device follows the Requirements and the Test Methods listed in the Attachment.

Description	***Diving accessories: " "***
Type	***"Name"***
Applicant	***"Company"*** ***"Address"***
Manufacturer	***"Company"*** ***"Address"***
Reference standards	***EN nnn:year***

Issuing this Statement, RINA Services S.p.A. doesn't act as a Notified Body.
This Statement is not to be considered as a Statement of conformity to the European Regulation.
The validity of this Statement is subjected to the maintenance of the initial product conditions verified by RINA Services S.p.A. according to the related Technical Documentation

*Issued in **Genoa** on **MM dd, yyyy***

RINA Services S.p.A.

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This Statement consists of this page and 1 enclosure.

STATEMENT OF COMPLIANCE

No. **LABxxxxyyCS**

Enclosure - Page 1 of 1

PRODUCT	MODEL NUMBER/CODE
"Name"	nnn

TECHNICAL DOCUMENTATION EXAMINATION

-
-
-

TYPE EXAMINATION

Standard	Requirements	Test Methods	Description
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title
EN nnnn:yyyy	A.B	B.C	Test title

- RINA Test Report N° yyyyCS01xxxx issued on Month dd, yyyy.

Genoa MM dd, yyyy

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