



Rules for the certification of products intended for use in potentially explosive atmospheres according to Directive 2014/34/EU

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Technical Rules

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CHAPTER 1. - GENERAL

1.1

These Rules describe the procedures applied by RINA for ATEX Certification of products and/or their production in conformity with the requirements for their use in potentially explosive atmospheres as per Decree Law no. 85 of May 19, 2016, based on Directive 2014/34/EU (hereinafter referred to as 'Directive'), and the procedures to be followed by Organizations to apply for, obtain and maintain said certification.

For any matters not covered by this document, reference is to be made to the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION", current revision, available in the www.rina.org website.

1.2

For the certification activities, RINA applies its current fees, guaranteeing fairness and uniformity of application. RINA may legitimately refuse any applications for certification from Organizations subject to, or whose production or activity is subject to restriction, suspension or proscription by a Public Authority.

1.3

The certification issued by RINA refers to products and/or their production mentioned in the certificate of the applicant Organization, where Organization stands for a legally-recognized company, enterprise, firm, public or private, with its own functions and administration or an individual. In the presence of Organizations with several operative units, each operative unit can be defined as an Organization.

1.4

Any information acquired during the certification activity shall be considered and treated as confidential.

CHAPTER 2. - REFERENCE LEGISLATION

2.1

The legislation applicable to Certification in conformity with the ATEX Directive is listed here below:

- Decree Law no. 85 of May 19, 2016, based on Directive 2014/34/EU (published on G.U.C.E. no. L96 of March 29, 2014).
- Guide to the application of Directive 2014/34/EU of the European Parliament and Council of February 26, 2014, on the approximation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (second edition of December 2017).
- Guide to transition from ATEX Directive 94/9/EC to 2014/34/EU "GUIDANCE DOCUMENT ON THE ATEX DIRECTIVE TRANSITION FROM 94/9/EC TO 2014/34/EU".
- (EC) Regulation No. 765/2008 of the European Parliament and Council of July 9, 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) no. 339/93/EC.

CHAPTER 3. - SCOPE

3.1

These Rules apply to certification activities, carried out by RINA, of products covered by the scope of the Directive.

The primary purpose of the ATEX Directive is to ensure that the products to which it is applied and marketed within the European Community are safe; furthermore, the directive intends to ensure their free movement within the territories of the EU.

The Directive applies to product design, manufacture and conformity assessment.

These Rules lay down the modalities to follow to obtain and maintain certification. They are applied starting from the issue date.

3.2

The product conformity certificate issued by RINA certifies that the products mentioned therein, if used in conformity with their destination, meet the essential health and safety requirements specified in annex II of the Directive.

3.3

The production conformity certificate issued by RINA certifies that the production mentioned therein meets the requirements specified in annexes IV to VII of the Directive.

3.4

The Directive also provides for the issue of depository receipts of technical documents as prescribed by Art. 13, paragraph 1 b ii of Directive 2014/34/EU.

3.5

The Certificate may attest conformity of:

- a) a single design applicable to all relating products;
- b) a basic design applicable to a homogeneous set of products, but different from one another for a limited set of characteristics (size, main dimension, variants, etc.);
- c) a management system of product quality or production quality;
- d) a single product (unique product).

CHAPTER 4. - FIELD OF APPLICATION

4.1 General

These Rules apply to the certification activities carried out by RINA of products covered by the scope of the Directive and namely:

- Equipment and protective systems intended for use in potentially explosive atmospheres;
- Safety devices, controlling devices and regulating devices intended for use outside potentially explosive atmospheres, but required for or contributing to the safe functioning of equipment or protective systems with respect to the risks of explosion;
- Components intended to be incorporated into equipment and protective systems referred to in the first paragraph.

4.2 Definitions

Equipment: machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy and/or the processing of material and which are capable of causing an explosion through their own potential sources of ignition. [art.2 c.1]

Protective systems: devices other than components of equipment which are intended to halt incipient explosions immediately and/or to limit the effective range of an explosion and which are separately made available on the market for use as autonomous systems. [art.2 c.2]

Components: any item essential to the safe functioning of equipment and protective systems but with no autonomous function. [art.2 c.3]

Explosive atmosphere: a mixture with air, under atmospheric conditions, of flammable substances in the form of gases, vapours, mists or dusts in which, after ignition has occurred, combustion spreads to the entire unburned mixture. [art.2 c.4]

Potentially explosive atmosphere: an atmosphere which could become explosive due to local and operational conditions. [art.2 c.5]

Equipment-group I: equipment intended for use in underground parts of mines, and in those parts of surface installations of such mines, liable to be endangered by firedamp and/or combustible dust, comprising equipment categories M 1 and M 2 as set out in Annex I. [art.2 c.6]

Equipment-group II: equipment intended for use in other places liable to be endangered by explosive atmospheres, comprising equipment categories 1, 2 and 3 as set out in Annex I. [art.2 c.7]

4.3 Exclusions

For any exclusions from the scope of the Directive reference should be made to article 1, paragraph 2 of the Directive.

4.4 Requirements

The ATEX Directive does not provide specific technical information about calculation, production and control methods to be adopted, but sets out essential health and safety requirements for the design and manufacture of equipment and protective systems intended for use in potentially explosive atmospheres, which are applicable, if required, also to safety, controlling and regulating devices.

The products compliant with harmonized standards the reference of which has been published in the Official Journal of the European Communities or with national standards based on a harmonized standard are deemed to be compliant with the Essential Health and Safety Requirements of annex II to the Directive.

The documents listed in Chapter 5 below, duly filled in by the Organization and with the relevant acceptance by RINA, when required, contractually formalize RINA's activities performed according to these Rules.

RINA requests, for examination purposes, the documents detailed in the annexes to these Rules, which are applicable according to the selected module.

4.5 Recommendations to the Manufacturer

Without prejudice to the fact that the provisions of the Directive and its annexes are equally important and applicable, it is appropriate to consider some aspects of the Directive relating to the following major subjects for product conformity certification purposes:

4.5.1 Risk analysis

To comply with the requirements of the Directive it is necessary to assess the risks relating to all the life stages of a product and to the production, transport, installation, operation and maintenance stages.

The risk analysis shall highlight all possible risks during the various applications of the product and in the presence of all reasonably foreseeable incorrect applications.

The risk analysis must be drafted by the manufacturer.

It is necessary to keep in mind that the risk analysis document is part of the Technical File to be submitted, if requested, to the competent authority.

4.5.2 Essential Health and Safety Requirements

The Essential Health and Safety Requirements are provided in Annex II to the Directive and, if applicable, must be complied with by the manufacturer.

The manufacturer shall draft a document that lists all the essential requirements of the Directive and, for each of them, provides the evidence of their fulfillment.

This document is part of the Technical File.

4.5.3 Tests and checks on products

Tests and checks on products are defined according to the various types of products considered, with reference to applicable standardization documents, and aim at verifying the total conformity of the product with the reference standards or with the Essential Health and Safety Requirements of the Directive (type tests) or at checking the product after manufacture (single tests).

CHAPTER 5. - APPLICATION FOR CERTIFICATION

The manufacturer or an authorized representative shall apply for certification to RINA on a specific document [ATX-DOM-CERT], which contains the following main general data:

- name and address of the manufacturer or its authorized representative established in the Community;
- the main characteristics of the product;
- the conformity assessment procedure that it intends to adopt;
- the presence of a certified management system in accordance with the ISO 9000 standards;

- a declaration stating that it did not submit the same application to another Body;
- any company or self-employed professionals who have been entrusted by the Organization with any activity concerning design / manufacture / installation / maintenance / distribution of the product and/or drafting of technical documents relating to the certification scope.

The application must be provided with the technical documents specified in the annexes to these Rules (Annexes III to IX) which describe each of the module dealt with by the Directive.

The document required for the application shall be sent by RINA to the manufacturer together with the offer concerning the certification activities in accordance with ATEX Directive 2014/34/UE and a copy of these Rules (if the manufacturer cannot download it from the rina.org website) and of the annexes relating to the applicable Conformity Assessment forms.

Upon reception of the “Application form for ATEX Certification” [ATX-DOM-CERT] duly filled in for acceptance of the relevant offer, RINA shall raise any comments or reject said requests within 5 working days; after this period of time has elapsed without any communications by RINA, the application will be automatically accepted, therefore RINA’s activities carried out in accordance with these Rules shall be deemed to be contractually formalized.

The “Application form for ATEX Certification” duly filled in by the Organization and the relevant acceptance by RINA contractually formalize RINA’s activities performed in accordance with these Rules.

RINA requests, for examination purposes, the documents detailed in the annexes to these Rules, applicable according to the selected module or set of selected modules.

RINA shall inform the Organization of the name of the file manager and the file manager will then inform the Organization of the name(s) of the technician(s) who will carry out the expected audits to the workshop and/or yard; the Organization may object to the appointment of these technicians, justifying the reasons for this objection.

CHAPTER 6. - CONFORMITY ASSESSMENT PROCEDURES

The ATEX Directive defines seven different conformity assessment procedures and describes which procedures can or must be adopted depending on the equipment-group or category of the products.

The following procedures are envisaged by the Directive:

- a) EU-type examination (*Annex III* of the Directive - Module B);
- b) Conformity to type based on quality assurance of the production process (*Annex IV* of the Directive - Module D);
- c) Conformity to type based on product verification (*Annex V* of the Directive - Module F);
- d) Conformity to type based on internal production control plus supervised product testing (*Annex VI* of the Directive - Module C1);
- e) Conformity to type based on product quality assurance (*Annex VII* of the Directive - Module E);
- f) Internal production control (*Annex VIII* of the Directive - Module A);
- g) Conformity based on unit verification (*Annex IX* of the Directive - Module G).

6.1 Criteria for the selection of Conformity Assessment Procedures

Once the product has been classified according to its group or category, the manufacturer or its authorized representative established by the Community can select the conformity assessment procedure using the “Modules” specified in the Directive.

For selection purposes it is necessary to consider the possibilities envisaged by the Directive according to the risk category, namely:

- a) series or individual product production of the equipment being tested;
- b) presence or absence of a corporate quality system certified by an accredited Body in the European territory (the ACCREDIA accreditation is required for Italian Bodies).

It should be pointed out that for all modules or sets of modules envisaged by the Directive, the fundamental aspect is that each product must have been subject to an appropriate Risk Analysis and must be designed and manufactured so as to meet all the applicable Essential Health and Safety Requirements, contained in Annex II of the Directive.

CHAPTER 7. - CONFORMITY ASSESSMENTS IN ACCORDANCE WITH ANNEXES IV and VII OF THE DIRECTIVE

With regard to Quality System Conformity Assessments (*Annex IV* or Module D - Conformity to type based on quality assurance of the production process; *Annex VII* or Module E - Conformity to type based on product quality assurance), if the documentation is successfully examined, RINA shall conduct an audit to the Organization, after communicating the names of the audit team members responsible for checking the correct application of all applicable procedures relating to design, manufacture and control of the products examined during the documental review.

The duration of the audit to the company depends on the conditions described in paragraphs 7.1 and 7.2 below and on the composition of the company's staff.

ACCREDIA personnel may take part in the audit together with RINA's audit team for witnessing/monitoring purposes.

The Organization may object to the appointment of these technicians, justifying the reasons.

This audit shall consist of:

- an initial briefing with the Organization to agree upon the auditing modalities;
- an inspection of the offices, production site(s) and, where necessary, installation site(s);
- a final meeting to illustrate the audit outcome.

RINA's audit team checks the adequacy of the Organization's Quality Management System against all applicable safety requirements, described in annex II of the Directive and, in the presence of any deficiencies or discrepancies with reference to what is declared on the system documentation, it may raise one or more nonconformities to the Organization.

During the audit, the Organization shall provide evidence of knowing all applicable reference standards, that its quality management system has been fully operating for at least three months and that this system and the relevant documented procedures are effectively applied.

For this purpose, also during surveillance audits (as specified below), RINA technicians must have free access to production areas, personnel and documentation and must have the required assistance by the personnel involved in the audit.

7.1

Whenever the Organization already holds a RINA-certified Quality Management System, the conformity assessment procedures in accordance with Annex IV (Conformity to type based on quality assurance of the production process) and Annex VII (Conformity to type based on product quality assurance) of Directive 2014/34/EU and the inspection audit shall focus, as far as applicable, on the conformity of the Management System with the CEI UNI EN ISO/IEC 80079-34 standard.

7.2

Whenever an Organization, with a currently valid certificate issued by another Body accredited by a signatory Body of the EA / IAF mutual recognition agreement, lodges its application for certification, RINA shall perform a check that includes:

- a review of the audit reports of previous inspection audits conducted by the accredited Body that issued the previous certificate.

The inspection audit will then proceed with the same modalities described in paragraph 7.

7.3

At the end of the assessment audit, the Organization will receive an audit report containing any raised non-conformities and recommendations.

The Organization may write its own reservations or observations concerning the findings raised by RINA in a dedicated space of the audit report.

The contents of this audit report are then confirmed by RINA in writing.

If RINA does not provide a written notice, the audit report is deemed to be confirmed after three working days from its delivery to the Organization.

After analysing the causes of any non-conformities written in the above audit report, the Organization shall propose the necessary corrective actions and the expected times for their implementation.

In the presence of A-type findings (see next paragraph) the certification process is suspended; in the presence of other findings, whose number may affect the correct operation of the system in the audit team's opinion, the certification process is suspended as well.

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

If the above term is exceeded, the FPC adopted by the Organization is subject to a complete review within 6 months from the date of the finding.

If said six-month period elapses without a positive conclusion of the assessment, RINA can close the certification file, charging the Organization with the costs incurred up to that point. In these cases, if the Organization intends to proceed with RINA certification, it must submit a new application and repeat the certification procedure.

The above time limits may, in specific cases, be changed upon the motivated request of the Organization, in RINA's judgement.

7.4

Any findings relating to the certification scope are divided according to the following types:

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

- the total disregard of one or more requirements of the reference standards;
- a situation that may cause the delivery of a product that does not comply with the current regulations of the Member State where the product is marketed;
- the disregard of one or more requirements of these Rules;
- a situation capable of causing a serious deficiency of the FPC system or reducing its capability to ensure control of the product to be marked.

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

- a condition that, in RINA audit team's opinion, according to their experience, cannot seriously affect the FPC system and reduce its capability to ensure control of the product(s).

(c) C-type findings (recommendations, observations):

- suggestions aimed at improving the system, which are not directly related to the provisions of the reference standards applicable to the product.

The presence of any findings raised during surveillance audits or unannounced audits is managed by RINA as follows:

In the presence of major nonconformities or other findings, whose number may affect the production process in the audit team's opinion, the Organization is subject to a supplementary audit within the times defined by RINA, depending on the type of non-conformities and, in any case, not later than three months from the end of the surveillance audit aimed at verifying the effectiveness of the corrections and proposed corrective actions.

If the nonconformities are not resolved within the established times or whenever the raised non-conformities do not ensure compliance of the product with the applicable standards, RINA may suspend certification until the non-conformities are corrected.

If also the following audit has a negative outcome, RINA will revoke the certificate of conformity.

7.5

Following the successful outcome of all examinations and tests stated in the annexes to these Rules, RINA will issue the certificate/authorization/approval related to the selected assessment module.

If the outcome is negative, RINA will inform the Organization of this result and agree upon the modalities for a possible repetition of the test.

7.6

The Organization shall ensure that the Notified Body can gain access to the applied and approved Quality System Documentation (paragraph 4.2 of the relevant annexes IV and VII of Directive 2014/34/EU).

In order to allow RINA to perform its surveillance activity on the quality system, the Organization is requested to keep available AT ITS OWN PREMISES a copy of the documentation sent to apply for certification and of the approved documentation following some subsequent changes to the system.

The documentation that shall be made available is listed in paragraph 3.2 of annexes IV and VII of Directive 2014/34/EU.

CHAPTER 8. - MARKING

CE marking shall be affixed on all products except components.

The CE marking affixing modalities are laid down in article 16 of the Directive and of annexes IV, V, VI, VII, VIII and IX of the Directive.

CHAPTER 9. - CERTIFICATION VALIDITY PERIOD

The certificate issued by RINA has the following validity:

- three years, for the activities mentioned in Annexes IV and VII of the Directive.
- ten years, for the activities mentioned in Annex III of the Directive.

The other types of certificates issued by RINA within this framework do not expire.

CHAPTER 10. - CERTIFICATION MAINTENANCE

The Organization shall ensure that the products are compliant with the applicable reference standards.

The Organization undertakes to inform RINA of any significant change to the product that may affect the requirements based on which it was certified.

The Organization must keep records of any claims received from its own customers concerning the products covered by the certificate and of the relevant corrective actions taken; these records must be kept available to RINA.

RINA reserves the right to perform additional audits to the Organization if it receives any claims or reports, which it deems to be particularly significant, relating to the non-compliance of the products with the requirements of the reference standards and of these Rules.

If the Organization refuses the above audits without a justified reason, RINA can start the certification suspension procedure.

If any claims or reports are deemed to be justified by RINA, the cost of the supplementary audit is charged to the Organization.

Whenever, during the certificate validity period, any changes are made to the certification requirements of the applicable standards or the certification scheme, RINA will decide whether it is necessary to perform additional checks and, if so, RINA will inform the Organization to define the actions to take or any additional audits.

CHAPTER 11. - CERTIFICATE EXTENSION

The applicant can submit a request to extend the EU-type examination certificate (Annex III) or the certificate of conformity of a single product (Annex IX) to attest conformity of the same design with further editions of the standard or with new standards.

The applicant shall request RINA for the extension of any certificates of products whose design was submitted to changes that may affect conformity with the essential requirements or whose application has been changed with reference to what stated in the certificate.

The documentation shall be submitted to RINA which performs all the checks required to issue the certificate. If the result of the checks confirms that also the new changes comply with the requirements of the reference standard, RINA will grant an extension of the existing conformity certificate.

The applicant shall also inform RINA if it intends to start production of new products or changed products if compared with the certified ones, which may request the extension of the product or production quality assurance notifications and shall draw up new or modified production plans.

When the production conformity certificate is based on the surveillance procedures laid down in Annex IV or VII, the applicant shall inform RINA of any changes to be made to the quality system of its production sites before implementing them. When a certificate is based on the surveillance procedure laid down in Annex VI, the applicant

shall inform RINA of any changes to be made to the quality system of the laboratories used for the tests before implementing them.

The documentation with changes and new or modified production plans shall be submitted to RINA that checks them, decides whether a new audit is required and informs the manufacturer.

If the result of the audits confirms that the changes to the quality system and the production plans comply with the requirements of the reference standard, RINA grants an extension of the existing production conformity certificate.

Any extension requests relating to:

- certificates of another type with respect to the original one;
- new applicants with respect to the one stated in the original certificate;
- conformity of a single product or a different design;
- production conformity assessment certificate for a different procedure with respect to the original one;

are treated as new applications for certification.

CHAPTER 12. - RECEIPT FOR REGISTRATION OF THE TECHNICAL FILE

The applicant shall submit to RINA a duly filled-in application for each receipt that it intends to obtain together with a declaration of acceptance of these Rules. The application shall clearly identify the products to which the technical documents refer, to allow for their recording and traceability. Upon receiving the technical documents, which must be sealed by the applicant, RINA issues a receipt, registers and files the documents.

RINA does not check the completeness and correctness of the technical documents.

Before the ten-year period expires, RINA asks the applicant to confirm its interest to keep the technical documents archived.

CHAPTER 13. - STORAGE OF SAMPLES AND DOCUMENTS

RINA ensures that samples are correctly handled during the checks. Storage of samples subject to tests at RINA's or manufacturer's premises is not required. A copy of the certificates and significant technical documents listed in the certificates are kept by RINA for four years after the expiry date of the certificate.

RINA ensures storage of technical documents for four years after informing the manufacturer of the expiry of the storage period or the absence of a confirmation by the manufacturer to be interested in keeping these documents.

When the above periods of time have elapsed without any further communications by the manufacturer, RINA can destroy the documentation.

CHAPTER 14. - SUSPENSION, REINSTATEMENT, WITHDRAWAL, RENUNCIATION AND REFUSAL OF CERTIFICATES

In case of suspension, withdrawal or renunciation of its certificate, the manufacturer shall inform RINA of the presence of manufactured and marked products ready to be placed on the market whose marketing authorization will be specifically evaluated by RINA.

The manufacturer shall also stop the CE marking of any products being manufactured starting from the suspension/withdrawal date.

14.1 Suspension

The validity of the certificate of conformity can be suspended in accordance with the requirements of the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEMS, PRODUCTS, PERSONNEL AND INSPECTION" and in the following specific cases:

- if the Organization does not allow the scheduled audits to be performed with the required frequency;
- if any non-conformities are found in the Quality Management System that are not solved within the terms established by RINA;
- if the Organization has not observed the times established for communicating the corrective actions, following any non-conformities/observations written in the audit report;
- if the Organization has undertaken major restructuring of its Site(s), moves to other site(s) without informing RINA of these changes;

- if the Organization has made major changes to its Quality Management System that have not been accepted by RINA;
- in the presence of major changes to the Organization that were not made known to RINA;
- if the Organization refuses or hinders the participation of the observers of an Accreditation Body;
- in the presence of an evidence that the Quality Management System does not ensure compliance with the laws and regulations applicable to the activities and/or the site(s);
- for any consequences related to non-acceptance by the Organization of the changes to the product due to updated standards/laws communicated by RINA;
- acknowledgment of any justified and serious claims received by RINA.

The Organization can also ask RINA, justifying the reasons for this request, to suspend its certificate for a period that generally does not exceed six months and, in any case, not after the expiry date of the certificate.

Suspension is notified in writing, with the conditions for reinstatement and the date within which they must be reached.

The certificate validity suspension can be made public by RINA.

The certificate suspension entails that the certificate cannot be used in association with the products. The suspension can be cancelled when the non-conformities that caused it are solved. Otherwise, RINA can withdraw the certificate.

14.2 Reinstatement

Reinstatement of the certificate is subject to verification that the deficiencies that led to the suspension have been solved by checking the product and the Organization to verify compliance of the product and Organization with all the requirements of the reference standard.

It is notified to the Organization in writing and is made public by RINA if the notice of suspension was also made public.

Failure to comply with the conditions of p. 14.1 within the established term causes the certificate of conformity to be withdrawn.

14.3 Withdrawal

Withdrawal of the certificate of conformity can be decided in accordance with the requirements of the “GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION” and in the following specific cases:

- when the validity period of the certificate has elapsed;
- for production conformity certificates in the event of termination of the manufacturer’s activity;
- in the presence of any situations, such as those laid down in p. 14.1 for suspension, which have been deemed particularly serious;
- if the Organization suspends its activities or services covered by the certified Quality Management System and/or the assessment of conformity of equipment and protective systems intended for use in potentially explosive atmospheres for a period greater than six months;
- whenever the Organization does not accept the new economic conditions established by RINA for possible amendment to the contract;
- for any consequences related to non-acceptance by the Organization of any changes to the product due to updated standards/laws notified by RINA;
- for any other serious reason in RINA’s opinion such as, but not limited to, the proved inability of the system to pursue its own objectives of compliance with the legal or contractual constraints or product safety requirements.

In case of withdrawal of the certificate of conformity, RINA undertakes to:

- a. provide the Organization in writing with detailed reasons for the decision of this withdrawal stating the possibility to appeal against this decision;

b. if the appeal is not successful, directly inform the Ministry for Economic Development, providing details of withdrawn certificates.

If an Organization intends to apply for certification again, it must submit a new application according to the entire procedure laid down in these Rules.

The withdrawal of a certificate has the following consequences:

- the prohibition to use the certificate in association with the products manufactured starting from the withdrawal notification date;
- the removal, by the certificate holder, of any reference to the certificate in catalogues and commercial documentation;
- the cancellation of the product from the list of RINA-certified products and the publication by RINA of the withdrawal notification in its website and/or by other means.

14.4 Renunciation

The certificate can be renounced by the holder:

- when it expires, with at least a two months' notice;
- in the presence of any changes to the reference standardization documents, when it does not intend to meet the new technical requirements;
- in the presence of substantial changes to these Rules, when it does not accept the new conditions.

The renunciation of a certificate has the following consequences:

- the prohibition to use the certificate in association with the products manufactured starting from the renunciation notification date;
- the removal, by the certificate holder, of any reference to the certificate in catalogues and commercial documentation;
- the cancellation of the product from the list of RINA-certified products and the publication by RINA of the renunciation notification in its website and/or by other means.

RINA informs the competent Administrations (Accredia, other notified Bodies, European Commission) of the expiry of the certificate validity, also prescribing, if appropriate, that the Organization takes any actions towards those products that have been already manufactured.

The Organization which renounces its certificate must return it to RINA.

If an Organization intends to apply for certification again, it must submit a new application according to the entire procedure laid down in these Rules.

A certified Organization cannot make use of its certificate and any copies of the same when the certificate is cancelled.

14.5 Refusal

Whenever the issue of a certificate is refused, RINA shall provide detailed reasons for this refusal. In this case the Organization can start an appeal procedure as described in the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION".

CHAPTER 15. - LISTED OF ISSUED CERTIFICATES

RINA periodically sends a list of issued certificates to the competent Ministry.

The above list can be published by RINA in its website.

This list includes:

- the Organization's name and address;
- the certificate number;
- a description of the certified product;
- the date of issue of the certificate;
- the expiry date of the certificate.

CHAPTER 16. - TRANSFER OF A CERTIFICATE

If the company name changes, the Organization shall inform RINA of said change by sending the following documentation:

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

After making the necessary checks, RINA will issue a new certificate of conformity cancelling the previous one.

CHAPTER 17. - APPEALS - COMPLAINTS

The Organization may appeal against RINA's decisions or submit a complaint in accordance with the requirements laid down in the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION".

CHAPTER 18. - ADVERTISING - USE OF RINA CERTIFICATES, USE OF THE LOGO

The Organization shall refer to the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION".

CHAPTER 19. - DEFINITIONS

- RT Technical Manager: a RINA employee responsible for the technical activities as per D.L. 85/2016 within the Italian Republic.
- SM: Member State of the European Union.
- FPC: Factory Production Control.

Annex III - EU-type examination

With regard to this procedure RINA verifies and attests that a specimen, representative of the production envisaged, meets the requirements of the Directive.

The manufacturer or its authorized representative in the European Community lodges an application for EU-type examination [Form ATX-DOM-CERT] attaching, for each 'type', the following documents:

- a) a general description of the product;
- b) nominal characteristics and protection method;
- c) conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits etc., complete with descriptions and explanations required for the understanding of these drawings and schemes and the product operation;
- d) a list of standards applied in full or in part to meet the essential requirements of the Directive if no harmonized standards have been applied;
- e) result of design calculations,
- f) test reports

The Applicant shall provide RINA with a declaration attesting that the same application for certification has not been lodged with any other notified Body within the European Union.

Furthermore, the applicant shall make available, in accordance with the reference standards, one or more specimens representative of the production, hereinafter referred to as "type". The same type may cover several versions of the product provided that the differences between the versions do not affect the level of safety.

Then RINA shall:

- examine and assess the documentation, to verify its correctness to provide a complete and correct definition of explosion safety and check that all aspects of the design comply with the applicable standards or with the requirements of the Directive, then send any comments;
- verify, by visual and dimensional checks, that the type was manufactured in compliance with the technical documents, and identify the elements which have been designed in accordance with the harmonized standards, as well as the elements which have been designed in accordance with other reference standards;
- carry out appropriate examinations and tests, or have them carried out, to check compliance with the applicable standards or the applicable essential safety requirements listed in Annex II of the Directive;
- agree with the manufacturer on a location where the examinations and tests will be carried out.

RINA shall draw up an evaluation report that records the activities undertaken in accordance with the previous paragraph and their outcomes. Without prejudice to its obligations vis-à-vis the notifying Bodies, RINA shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

If the checks and tests have positive outcomes, RINA shall issue an EU-type examination certificate to the applicant. That certificate shall contain the name and address of the applicant, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The EU-type examination certificate may have one or more annexes attached.

The EU-type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the Directive, RINA shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

RINA shall keep itself apprised of any changes in the generally acknowledged state of the art and assess whether the approved type does no longer comply with the applicable requirements of the Directive. RINA shall determine whether such changes require further investigation. If so, RINA shall inform the manufacturer accordingly.

The applicant shall inform RINA, which holds the technical documentation relating to the EU-type examination certificate, of all modifications to the approved type that may affect the conformity of the product with the essential health and safety requirements or the conditions of validity of this certificate. Such modifications shall require additional approval in the form of an addition to the EU-type examination certificate.

RINA shall inform its notifying authority concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

RINA shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

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

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

The applicant shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

Annex IV - Quality assurance of the production process

The manufacturer ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of this Directive that apply to them.

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the products concerned as specified in the next paragraph and shall be subject to surveillance as specified in paragraph “surveillance”.

Quality system

The manufacturer shall lodge an application for assessment of his quality system for the products concerned. The application shall include:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- b) a general description of the product;
- c) the identification of the production sites;
- d) a written declaration that the same application has not been lodged with any other notified body;
- e) all relevant information for the product category envisaged;
- f) a copy of the quality manual and the relevant procedures/instructions for the ATEX certification;
- g) a copy of the EU-type examination certificate;
- h) a copy of the ISO 9001 certificate issued by a national or international accredited certification Body;
- i) a copy of any certificates issued by notified Bodies to the quality system of the production units in compliance with the Directive

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

The quality system documentation shall contain an adequate description of:

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

The quality system shall ensure conformity of the products with the type covered by the EU-type examination certificate and with the essential applicable requirements. It is necessary for the manufacturer to have its own

quality system certified, possibly in accordance with the ISO 9001 standard, by an accredited Body; other situations will be evaluated on a case-by-case basis.

RINA shall check all the technical documentation received to verify that it appropriately describes what is requested and that the selected attestation procedure complies with art. 13 of the Directive and shall send any observations to the manufacturer.

When the manufacturer deems to have aligned the documentation of his company quality system with the ATEX requirements, he asks RINA to carry out the audit.

During the first certification audit RINA shall assess the fundamental issues of the Quality System against the requirements of the ATEX Directive by a specific checklist and shall also assess the Quality System if it has been certified by a Body other than RINA. At the end of the audit RINA shall issue a copy of the Audit Report to the Organization.

RINA checks the quality system in accordance with the Rules for the certification of Quality Systems issued by RINA.

RINA also verifies compliance of test laboratories with the requirements of the ISO/IEC 17025 standard and checks that the quality control procedures ensure the correct conduction of tests and examinations of the products specified in the EU-type examination certificate.

The audit team shall have at least one member with experience of the production technology relating to the equipment concerned. The auditing activity shall include an assessment visit to the manufacturer's premises.

If the auditing activities are successfully completed, i.e. if minor findings (B type) or recommendations have been raised, RINA shall issue a Warranty Notification of the production process quality. RINA shall perform a new audit to verify that the changes agreed upon during the audit have been implemented within the agreed terms.

In the presence of major findings or several minor findings that may affect compliance with the Essential Safety Requirements, RINA shall conduct another audit within the date written in the Audit Report (so as to allow the manufacturer to operate on his quality system integrating the requested changes) and shall issue no Warranty Notification of the production process quality.

After the second audit is completed, if the outcome is positive or if it falls within the above limits, RINA shall issue a Warranty Notification of the production process quality.

The Warranty Notification of the production process quality is valid for three years.

Should also the second audit have a negative outcome, RINA shall inform the other Notified Bodies of the absence of Warranty Notification of the production process quality.

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

The manufacturer or the authorized representative in the Community shall keep RINA that has approved the quality system informed of any intended change to the quality system.

RINA shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements mentioned above or whether another reassessment is necessary.

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

Surveillance

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

Surveillance of the quality system is performed by RINA according to a schedule that foresees a maintenance audit at the end of the first year, a maintenance audit at the end of the second year and a series of unexpected audits equal to at least 1 audit/year and conducted by product specialists.

During each maintenance audit, RINA totally verifies the company quality system or applies a review program to have the QMS totally re-examined during the two audits.

Unexpected audits shall ensure that each type of product is checked at least once per year. The number of unexpected audits is determined according to this information:

- the group and category of the product;
- the results of previous surveillance audits;
- the need to ensure implementation of corrective actions;
- if applicable, any special conditions related to system approval;
- significant changes to the directives or manufacturing techniques.

On occasion of unexpected and unannounced audits conducted by RINA, the manufacturer shall make available the following documentation:

- quality system documentation
- internal inspection reports
- conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits etc., complete with descriptions and explanations required for the understanding of these drawings and schemes and the equipment operation
- traceability procedures
- calibration certificates of test equipment
- any non-conformity reports issued during production and related resolutions
- operating instructions (assembly and start up, operation and maintenance, limits of use, residual risks related to the use, identification of replaceable parts, documents required for the total understanding of these instructions)
- declaration of conformity.

Annex IV - Module D - Quality assurance of the production process

The manufacturer shall affix the CE marking and, under RINA's responsibility, the latter's identification number to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the Directive.

The manufacturer shall draw up a written EU declaration of conformity for each product model, other than a component and keep it at the disposal of the national authorities for 10 years after the product other than a component has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product, other than a component.

The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

- a) the documentation referred to in the above "quality system" paragraph;
- b) the information relating to any changes to the quality system and the relevant approval;
- c) the decisions and reports issued by RINA.

RINA shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

RINA shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Annex V - Product verification

Conformity to type based on product verification is the part of a conformity assessment procedure whereby the manufacturer or his legal representative within the Community ensures and declares that the products subject to surveillance activities performed by RINA and described in the “Product verification” paragraph are in conformity with the type described in the EU-type examination certificate and satisfy the applicable essential requirements.

The manufacturer shall lodge an application for product verification enclosing, for each type of product to which he intends to affix the CE marking, the following documentation:

- a general description of the product;
- the identification of the production sites;
- the used attestation procedure (for CE marking and related Declaration of conformity);
- conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits etc., complete with descriptions and explanations required for the understanding of these drawings and schemes and the product operation;
- a copy of the EU-type examination certificate issued by a Notified Body with all related technical documents.

RINA examines the above documentation and sends any comments.

Furthermore, the manufacturer shall take all necessary measures so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the EU-type examination certificate and with the applicable requirements of the Directive.

Product verification

All products shall be individually examined by RINA and appropriate tests set out in the relevant harmonised standards and/or equivalent tests set out in other relevant technical specifications shall be carried out to verify conformity with the approved type described in the EU-type examination certificate and with the appropriate requirements of the Directive.

In the absence of such a harmonised standard, RINA shall decide on the appropriate tests to be carried out.

If the outcome of these tests is satisfactory, RINA shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to each approved product or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity available for inspection by the national authorities for 10 years after the product has been placed on the market.

CE marking, EU declaration of conformity and attestation of conformity

The manufacturer shall affix the CE marking and, under RINA’s responsibility, the latter’s identification number to each individual product other than a component that is in conformity with the approved type described in the EU-type examination certificate and satisfies the applicable requirements of the Directive.

The manufacturer shall draw up a written EU declaration of conformity for each product model other than a component and keep it at the disposal of the national authorities, for 10 years after the product, other than a component, has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.



A copy of the EU declaration of conformity shall accompany every product other than a component.

If RINA agrees and under his responsibility, the manufacturer may also affix RINA's identification number to the products other than components.

The manufacturer shall draw up an attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

If RINA agrees and under his responsibility, the manufacturer may affix RINA's identification number to the products during the manufacturing process.

Annex VI - Internal production control plus supervised product testing

Conformity to type based on internal production control plus supervised product testing is the part of an assessment procedure whereby the manufacturer or his legal representative within the Community ensures and declares that the products are in conformity with the type described in the EU-type examination certificate and satisfy the applicable requirements of the Directive.

The manufacturer shall lodge an application for conformity to type enclosing, for each type of product to which he intends to affix the CE marking, the following documentation:

- a) a general description of the product;
- b) conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits etc., complete with descriptions and explanations required for the understanding of these drawings and schemes and the product operation;
- c) a list of standards applied in full or in part and the descriptions of the solutions adopted to meet the essential requirements of the Directive if no harmonized standards have been applied;
- d) the identification of the test laboratories at which the tests prescribed for the selected attestation procedure shall be carried out;
- e) the attestation procedure adopted (for CE marking and relevant Declaration of conformity);
- f) any technical documentation relating to the approved type;
- g) a copy of the quality manual and significant procedures/instructions with reference to ATEX requirements;
- h) a copy of the EU-type examination certificate;
- i) a copy of any ISO 9001 certificate issued by a national or international accredited certification Body;
- j) a copy of any attestations issued by notified Bodies to the quality system of the production units in accordance with the Directive
- k) a copy of any accreditation certificate in conformity with the ISO/IEC 17025 standard of test laboratories issued by a national or international accreditation Body

Product checks

For each individual product manufactured one or more tests on one or more specific aspects of the product shall be carried out by the manufacturer in order to verify conformity with the type described in the EU-type examination certificate and with the applicable requirements of the Directive. The tests shall be carried out under RINA's responsibility.

The manufacturer shall, under RINA's responsibility, affix the RINA's identification number during the manufacturing process.

If the outcome of these activities is successful RINA issues a conformity to type report.

CE marking

The manufacturer shall affix the CE marking to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the Directive.

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

A copy of the EU declaration of conformity shall accompany every product, other than a component.

The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

Annex VII - Product assurance quality

Conformity to type based on product quality assurance is that part of a conformity assessment procedure whereby the manufacturer fulfils the production and marking obligations and ensures and declares on his sole responsibility that the products concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of the Directive that apply to them.

Manufacturing

The manufacturer shall operate an approved quality system for final product inspection and testing of the products concerned, as specified below, and shall be subject to surveillance.

Quality System

The manufacturer shall lodge an application for assessment of his quality system for the products concerned enclosing the following documents:

- a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- b) a general description of the product;
- c) the identification of the production sites;
- d) a written declaration that the same application has not been lodged with any other notified body;
- e) all relevant information for the product category envisaged;
- f) a copy of the quality manual and significant procedures/instructions for ATEX certification;
- g) a copy of the EU-type examination certificate.

The quality system shall ensure compliance of the products with the type described in the EU-type examination certificate and with the applicable requirements of the Directive.

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

The quality system documentation shall contain an adequate description of:

- the quality objectives and the organisational structure, responsibilities and powers of the management regarding product quality;
- the examinations and tests that will be carried out after manufacture;
- the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.;
- the means of monitoring the effective operation of the quality system.

When the manufacturer deems to have aligned the documentation of his company quality system with the ATEX requirements, he asks RINA to carry out the audit.

RINA examines the received documentation to verify that it appropriately describes what is requested and that the selected attestation procedure is in conformity with art. 13 of the Directive and sends any observations to the manufacturer.

During the first certification audit RINA shall assess the fundamental issues of the Quality System against the requirements of the ATEX Directive by a specific checklist and shall also assess the Quality System if it has been certified by a Body other than RINA. At the end of the audit RINA shall issue a copy of the Audit Report to the Organization.

RINA checks the quality system in accordance with the Rules for the certification of Quality Systems issued by RINA.

RINA also verifies compliance of test laboratories with the requirements of the ISO/IEC 17025 standard and checks that the quality control procedures ensure the correct conduction of tests and examinations of the products specified in the EU-type examination certificate.

The audit team shall have at least one member with experience of the production technology relating to the equipment concerned. The auditing activity shall include an assessment visit to the manufacturer's premises.

The quality system shall ensure conformity of the products with the type covered by the EU-type examination certificate and with the essential applicable requirements. It is necessary for the manufacturer to have its own quality system certified, possibly in accordance with the ISO 9001 standard, by an accredited Body; other situations will be evaluated on a case by case basis.

If the auditing activities are successfully completed, i.e. if minor findings (B type) or recommendations have been raised, RINA shall issue a Warranty Notification of the product quality. RINA shall perform a new visit to verify that the changes agreed upon during the audit have been implemented within the agreed terms.

In the presence of major findings or several minor findings that may affect compliance with the Essential Safety Requirements, RINA shall conduct another audit within the date written in the Audit Report (so as to allow the manufacturer to operate on his quality system integrating the requested changes) and shall issue no Warranty Notification of the product quality.

After the second audit is completed, if the outcome is positive or if it falls within the above limits, RINA shall issue a Warranty Notification of the product quality.

The Warranty Notification of the product quality is valid for three years.

Should also the second audit have a negative outcome, RINA shall inform the other Notified Bodies of the absence of Warranty Notification of the product quality.

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

The manufacturer or the authorized representative in the Community shall keep RINA that has approved the quality system informed of any intended change to the quality system.

RINA shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements mentioned above or whether another reassessment is necessary.

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

Surveillance

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

Surveillance of the quality system is performed by RINA according to a schedule that foresees a maintenance audit at the end of the first year, a maintenance audit at the end of the second year and a series of unexpected audits equal to at least 1 audit/year and conducted by product specialists.

During each maintenance audit, RINA totally verifies the company quality system or applies a review program in order to have the QMS totally re-examined during the two audits.

Unexpected audits shall ensure that each type of product is checked at least once per year. The number of unexpected audits is determined according to this information:

- the group and category of the product;
- the results of previous surveillance audits;
- the need to ensure implementation of corrective actions;
- if applicable, any special conditions related to system approval;
- significant changes to the directives or manufacturing techniques.

On occasion of unexpected and unannounced audits conducted by RINA, the manufacturer shall make available the following documentation:

- quality system documentation
- internal inspection reports
- conceptual design and manufacturing drawings, and schemes of components, sub-assemblies, circuits etc., complete with descriptions and explanations required for the understanding of these drawings and schemes and the equipment operation
- traceability procedures
- calibration certificates of test equipment
- any non-conformity reports issued during production and related resolutions
- operating instructions (assembly and start up, operation and maintenance, limits of use, residual risks related to the use, identification of replaceable parts, documents required for the total understanding of these instructions)
- declaration of conformity.

At the end of each audit RINA will issue a copy of the Audit Report.

The manufacturer shall affix the CE marking and, under RINA's responsibility, the latter's identification number to each individual product other than a component that is in conformity with the type described in the EU-type examination certificate and satisfies the applicable requirements of the Directive.

The manufacturer shall draw up a written EU declaration of conformity for each product model, other than a component and keep it at the disposal of the national authorities for 10 years after the product other than a component has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product, other than a component.

The manufacturer shall draw up a written attestation of conformity for each component model and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component model for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

The manufacturer shall, for a period ending 10 years after the product has been placed on the market, keep at the disposal of the national authorities:

- a) the documentation referred to in the above "quality system" paragraph;
- b) the information relating to any changes to the quality system and the relevant approval;
- c) the decisions and reports issued by RINA.

RINA shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of quality system approvals refused, suspended or otherwise restricted.

RINA shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Annex VIII - Internal production control

Internal production control is the conformity assessment procedure whereby the manufacturer or the authorized representative in the Community ensures and declares that the products satisfy the requirements of the Directive that apply to them.

The manufacturer or the authorized representative shall establish the technical documentation. The documentation shall make it possible to assess the product's conformity to the relevant requirements and shall include an adequate analysis and assessment of the risks.

The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

- 1) *a general description of the product;*
- 2) *conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.;*
- 3) *descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;*
- 4) *a list of the harmonized standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonised standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of the Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied;*
- 5) *results of design calculations made, examinations carried out, etc.;*
- 6) *test reports.*

The manufacturer shall affix the CE marking to each individual product other than a component that satisfies the applicable requirements of the Directive.

The manufacturer shall draw up a written EU declaration of conformity for a product model other than a component and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product, other than a component, has been placed on the market. The EU declaration of conformity shall identify such product model for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product other than a component.

The manufacturer shall draw up a written attestation of conformity for each component model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

If art. 13.1.b.ii of the Directive is applied (non-electrical products category M2 or 2), the manufacturer or the authorized representative in the Community shall submit the above technical documentation to RINA by sending it in a sealed envelope together with the application to keep this technical file and issue receipt for the same.

The application must clearly show the indication of the products to which the technical file refers.

RINA does not check the documentation contained in the technical file.

RINA shall issue a receipt concerning the archiving of the technical file and, before the ten years' period elapse, asks the applicant whether he intends to keep the technical file or not.

Annex IX - Unit verification

Unit verification is the conformity assessment procedure whereby the manufacturer ensures and declares that the product mentioned in the certificate of conformity issued by RINA satisfies the requirements of the Directive that apply to them.

The manufacturer shall establish the technical documentation and make it available to RINA. The documentation shall make it possible to assess the product's conformity with the relevant requirements and shall include an adequate analysis and assessment of the risks. The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain at least the following elements:

- a) a general description of the product;
- b) nominal characteristics and protection method;
- c) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc., complete with descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product;
- d) a list of the harmonized standards applied in full or in part the references of which have been published in the Official Journal of the European Union and, where those harmonized standards have not been applied, descriptions of the solutions adopted to meet the essential health and safety requirements of this Directive, including a list of other relevant technical specifications applied. In the event of partly applied harmonized standards, the technical documentation shall specify the parts which have been applied;
- e) results of design calculations made and examinations carried out;
- f) test reports

The manufacturer shall keep the technical documentation at the disposal of the relevant national authorities for 10 years after the product has been placed on the market.

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured product with the applicable requirements of the Directive.

RINA shall carry out appropriate examinations and tests, set out in the relevant harmonized standards and/or equivalent tests set out in other relevant technical specifications, to check the conformity of the product with the applicable requirements of the Directive, or have them carried out. In the absence of such a harmonized standard RINA shall decide on the appropriate tests to be carried out.

RINA shall issue a certificate of conformity in respect of the examinations and tests carried out and shall affix its identification number to the approved product, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the national authorities for 10 years after the product has been placed on the market.

The manufacturer shall affix the CE marking and, under RINA's responsibility, the latter's identification number to each product other than a component that satisfies the applicable requirements of the Directive.

The manufacturer shall draw up a written EU declaration of conformity and keep it at the disposal of the national authorities for 10 years after the product, other than a component has been placed on the market. The EU declaration of conformity shall identify such product for which it has been drawn up.

A copy of the EU declaration of conformity shall accompany every product, other than a component.

The manufacturer shall draw up a written attestation of conformity and keep it at the disposal of the national authorities for 10 years after the component has been placed on the market. The attestation of conformity shall identify the component for which it has been drawn up. A copy of the attestation of conformity shall accompany every component.

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