



Rules for the Assessment of Conformity of Machinery in accordance with Directive 2006/42/EC

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RINA Services S.p.A.
Via Corsica, 12 - 16128 Genova - Italy
Tel. +39 01053851 - Fax: +39 0105351000
www.rina.org

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CHAPTER 1 - GENERAL

1.1 – Scope

These Rules define the procedures applied by RINA Services S.p.A. (hereinafter referred to as RINA) for the assessment of conformity of machinery in accordance with the provisions of the Decree Law for the implementation of Directive 2006/42/EC on machinery amending Directive 95/16/EC on hoists and the modalities that Organisations must observe to request, obtain and maintain certification.

This Directive applies to the products mentioned in Art. 1 and Annex IV of Directive 2006/42/EC; the Directive establishes the essential health and safety requirements applicable to said products,

Certification can be requested by all Organisations irrespective of whether they belong to any Association or Group. With regard to the certification activity RINA shall apply these Rules to all clients in a uniform and impartial manner.

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

In order to ensure that the assessment methods adopted by RINA comply with the reference standards, the body guaranteeing the certifications issued (Accredia) may request the participation of its observers in the audits carried out by RINA.

The participation of observers in audits, including those of the Accreditation Body, is agreed in advance between RINA and the Organization.

The participation of any observers to the audits and/or any visit carried out directly through Accreditation Body's personnel is previously agreed between RINA and the Organisation.

If the Organisation refuses to accept the above, the assessment process is suspended until the Organisation grants its consent to the audit and for a maximum period of 3 months.

The terms used in these Rules are the same as Directive 2006/42/EC to which reference shall be made for the complete list.

In addition to certificate issue procedures, these Rules describe the modalities to request, obtain, maintain and use, as well as information on duration, suspension and withdrawal of this certification.

1.2 - Definitions

Machinery: an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;

an assembly referred to in the first indent, missing only the components to connect it on site or to sources of energy and motion;

an assembly of machinery referred or partly completed machinery which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;

interchangeable equipment which, after the putting into service of machinery or of a tractor, is assembled with that machinery or tractor by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool.

Safety component: a component which serves to fulfil a safety function, which is independently placed on the market, the failure and/or malfunction of which endangers the safety of persons, which is not necessary in order for the machinery to function, or for which normal components may be substituted in order for the machinery to function.

Partly completed machinery: an assembly which is almost machinery but which cannot in itself perform a specific application. Partly completed machinery is only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment thereby forming machinery.

Declaration of conformity: a declaration by the manufacturer or his authorised representative established in the European Community whereby, under his own responsibility, declares that the machinery or partly completed machinery placed on the market complies with all applicable essential health and safety requirements laid down in Directive 2006/42/EC.

Placing on the market: making available for the first time in the Community machinery or partly completed machinery with a view to distribution or use, whether for reward or free of charge. Any machinery or partly completed machinery, which is made available after being subject to any changes not scheduled by ordinary or extraordinary maintenance, is also considered as placed on the market.

Putting into service: the first use, in the Community, of machinery or partly completed machinery; the use of the machinery or partly completed machinery manufactured on the basis of the previous legislation and already operating on the entry into force of the Rule based on the Directive, whenever subject to changes in the operating modalities not directly envisaged by the manufacturer.

Harmonised technical standards: technical specifications adopted by European Standardisation Bodies, on the basis of a remit issued by the EU Commission and approved by it, the references of which are published in the EU Official Journal and implemented by a national standard.

CE marking: standardised marking indicating compliance of the machinery with the essential health and safety requirements of the Directive.

Annex III of the Directive and the applicable harmonised standard establish the affixing modalities for the marking, including any relevant information.

The manufacturer or his representative established in the Community only affixes the CE marking on machinery.

Presumption of conformity: Member states shall regard machinery manufactured in conformity with the applicable harmonised standards as complying with the essential health and safety requirements listed in Annex I of the Directive.

Manufacturer: the manufacturer of the machinery established in the European Community and any other person who manufactures machinery affixing his name, trademark or another distinctive sign on said machinery or any person who refurbishes the machinery; the manufacturer's representative if the manufacturer is not established in the European Community or, in the absence of a representative established in the Community, the importer of the machinery; other professional operators of the supply chain to the extent that their activity may affect the safety characteristics of the machinery placed on the market.

Notified Body: a body which, with the prior authorisation by the competent Ministry, performs certification activities; after issuing the authorisation the competent Ministry will inform the European Commission of the notified bodies for EC certification of conformity.

CHAPTER 2 – LEGISLATION AND REFERENCE STANDARDS

2.1 - Reference legal provisions

These Rules have been drawn up considering the following legal and standardisation documents:

- Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC (recast);

- Decree Law of 27 January 2010, no. 17 implementing Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery and amending Directive 95/16/EC on hoists;
- Reference standards for the certification of machinery as per art. 7, paragraph 2 of Directive 2006/42/EC;
- Other sectorial documents (regulatory mandates, interpretative documents, etc.).

CHAPTER 3 – CERTIFICATION OF MACHINERY INCLUDED IN ANNEX IV

This chapter describes the certification procedures applicable to the machinery listed in annex IV of Directive 2006/42/EC.

RINA can delegate to other persons or bodies (e.g. laboratories and external staff) the conduction of some activities while remaining responsible towards the client.

The main issues of the machinery verification and certification process are described below together with the two certification procedures laid down in the directive:

- EC-type examination
(Annex IX of the Directive – module B);

3.1 – Application for certification

The manufacturer or his authorized representative shall submit an application for certification to RINA on a specific document [Dom-MAC00], which contains the following main general data:

- name and address of the manufacturer or his authorized representative established in the Community;
- the main characteristics of the product;
- the conformity assessment procedure that he intends to adopt;
- a declaration stating that he did not submit the same application to another Body;
- any company or self-employed professionals who have been entrusted by the Organisation with any activity concerning design / manufacture / installation / maintenance / distribution of the product and/or drafting of technical documents relating to the certification scope.

For the machine for which type examination certification is requested, the technical file as described in Annex VII point a) of the Directive must be attached to the application.

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 Directive 2006/42/EC on machinery and a copy of these Rules.

Upon reception of the “Application form for Conformity Assessment of Machinery” [Dom-MAC00] 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 Conformity Assessment of Machinery” duly filled in by the Organisation and the relevant acceptance by RINA contractually formalize RINA’s activities performed in accordance with these Rules.

RINA shall inform the Organisation of the name of the file manager and the file manager will then inform the Organisation of the name(s) of the technician(s) who will carry out the expected audits to the workshop and/or yard; the Organisation may object to the appointment of these technicians, justifying the reasons for this objection within 10 days of receiving the communication.

Notifying Bodies’ or Accreditation Bodies’ personnel may take part in the audit together with RINA’s audit team for witnessing/monitoring purposes.

Following an agreement between the parties, the contract can be changed whenever the conditions on the basis of which RINA prepared its initial economic offer have significantly changed.

3.3 – EC-type examination

The manufacturer or his authorised representative submits a representative model ("type") of a machine referred to in Annex IV of the Directive to RINA; RINA ascertains and certifies that it satisfies the provisions of the Directive.

The manufacturer or his authorised representative must, for each type, draw up a technical file and make available a sample of the type to RINA; RINA may request other samples if the test program requires it.

RINA examines the technical file in accordance with the requirements of p. 3.3.1, checks that the type was manufactured in accordance with it and establishes which elements have been designed in accordance with the harmonized standards and those elements whose design is not based on the applicable provisions of the above standards.

RINA carries out appropriate inspections, measurements and tests or has them carried out in accordance with the requirements of p. 3.3.2, to ascertain whether the solutions adopted satisfy the essential health and safety requirements of the Directive and, if the harmonised standards have been applied, whether they have been correctly applied.

3.3.1 – Examination of the technical documentation

Upon or after acceptance of the offer, the Organisation must provide RINA with a copy of the technical file containing the documents specified in annex VII p. a) of the Directive.

The documentation is examined by a RINA competent technician.

The technical documentation is examined by RINA according to the requirements contained in the applicable reference standards and in Directive 2006/42/EC.

The outcome of the technical documentation assessment is reported to the Organisation; any findings raised must be solved by the Organisation before proceeding with certification.

The successful outcome of the technical documentation assessment is a necessary condition to continue the certification activity with the examination of the machinery.

The technical documentation is usually retained by RINA for a minimum period of 15 years.

In the presence of specific agreements with the Organisation, a part of the documentation can be directly examined at the Organisation's premises.

3.3.2 – Machinery inspection

If the documentation assessment has a positive outcome, RINA shall inspect the machinery by a qualified technician; this inspection is agreed upon with the Organisation.

When examining the machinery, RINA shall:

- ascertain that the machinery was manufactured in compliance with the technical manufacturing file and that it can be safely used in the expected operating conditions;
- verify whether, during the manufacturing of the machinery, the reference standardisation documents were correctly applied;
- have appropriate examinations and tests carried out to check conformity of the machinery with the applicable essential health and safety requirements.

The inspection of the machinery covers all the requirements of the applicable reference standards (harmonised standards if available or general requirements of applicable standards).

During the inspection the qualified technician can use a checklist to check all the applicable requirements.

If the harmonised standards require the conduction of laboratory tests, these tests shall be carried out (at the manufacturer's expenses) at an independent laboratory accredited in conformity with the UNI CEI EN ISO/IEC 17025 standard for the specific test and/or at the manufacturer's laboratory after RINA has verified that it is suitable for the expected tests.

Tests at the manufacturer's laboratory shall be carried out in the presence of RINA technical staff.

Prior to the execution of the test, RINA assesses the capacity of the laboratory used by the manufacturer for the specific test.

This preliminary assessment keeps into account at least the following issues:

1. Competence of the personnel qualified for the test
2. Suitability of the structures, equipment and environmental conditions
3. Test method
4. Traceability of measurements (calibration of the equipment must be referred to the international SI system)

3.5 – Issue of certification

Only if both the examination of the technical documents and the inspection of the machinery as per paragraphs 3.3.1 and 3.3.2 provide a successful result, the Scheme Manager or a delegated technician can proceed with the competent and independent technical verification of the entire file; if also this verification has a successful result, it is possible to issue the EC-type examination certificate.

The manufacturer must ask RINA to review the validity of the EC Type Examination Certificate by the expiry date (five years); if, taking into account the state of the art, the certificate remains valid, RINA will extend its validity for another five years. For each renewal following the first, RINA deems it necessary to thoroughly review both the documentation § 3.3.1 and the machinery § 3.3.2.

The manufacturer and RINA shall retain a copy of this certificate, of the technical file and of all the relevant documents for a period of 15 years from the date of issue of the certificate.

CHAPTER 4 – CERTIFICATION MAINTENANCE

4.1 – General conditions for certification maintenance

The Organization must maintain compliance with the applicable requirements (Annex I of the Directive) of the machines covered by the certification.

The Organisation must keep records of any claims received from its own customers concerning the machine 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 Organisation if it receives any claims or reports, which it deems to be particularly significant, relating to the non-compliance of the machines with the requirements of the reference standards and of these Rules.

If the Organisation 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 Organisation.

In the event of additional audits, or in the case of periodic or renewal audits to be conducted in the field at the Organisation, RINA communicates in advance the names of the assessment team in charge. The Organization may object to the appointment of the technicians in charge, justifying the reasons, within 10 days of the communication.

CHAPTER 5 – CERTIFICATION CHANGES

5.1 – Changes to certified machines or system

The Organization undertakes to communicate to RINA any significant changes it intends to make to the machinery produced. A significant change is considered to be such as to influence the security measures adopted to meet the requirements that determined the certification.

Depending on the type of proposed changes, RINA informs the Organisation of its own assessments and reserves the right to perform supplementary audits to evaluate the influence of the changes made; following additional checks, RINA may revise the certificate or start a new certification procedure.

If the company name changes, the Organisation 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.

5.2 – Changes to technical specifications and rules

RINA has the right to modify the certification system described in these Rules.

Any change made by RINA to its own provisions for certification attainment and maintenance, for example following the issue of new laws, is reported to all Organisations with RINA certificates, which must adjust to the new rules.

An Organisation which does not accept the new rules renounces its certification in accordance with the requirements laid down in chapter 7.

CHAPTER 6 - SUSPENSION, REINSTATEMENT AND WITHDRAWAL 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.

6.1 - Suspension

The validity of the issued certificate can be suspended in the following cases:

- if the Organisation does not keep any records of the claims and relevant corrective actions;
- if the Organization has made substantial changes to its machines that have not been accepted by RINA;
- in the presence of any justified and serious claims received by RINA;
- in the event of a misuse by the Organisation of RINA identification data to be affixed to the manufacturer's declaration of conformity for the CE marking of the machinery and/or of the certificate issued by RINA and if the Organisation did not take the measures requested by RINA;
- in the presence of an evidence that the characteristics of the machinery do not comply with the applicable laws and regulations;
- in the presence of any other condition that, in RINA's judgment, has a negative influence on the conformity of the machinery with the applicable standards.

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.

Suspension is notified in writing to the Organisation by registered letter, with the certificate reinstatement conditions and the date within which they must be reached.

The suspension of the certificate validity can be made public by RINA.

During the suspension period, the Organisation cannot make use of RINA certificate (certificate number, RINA id code, etc.) on manufacturer's declaration of conformity for the CE marking of the machine in question and on any other document.

6.2 - Reinstatement

Reinstatement of the certificate is subject to verification that the deficiencies that led to the suspension have been solved by a thorough examination aimed at checking that the machine complies with all the requirements of the reference standards.

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

6.3 - Withdrawal

Failure to fulfil the conditions within the deadline established by p. 6.2 causes the certificate to be withdrawn.

A certificate can be withdrawn also in the following cases:

- in the presence of any situations, such as those laid down in p. 6.1 for suspension, which have been deemed particularly serious;
- in the presence of a formal request from the Organisation, including when the Organisation does not intend or cannot accept the new RINA provisions (see Ch. 5);
- if the Organisation suspends the supply or the use of the certified machine;
- for any other serious reason in RINA's opinion.

The withdrawal is notified to the Organisation in writing by registered letter and is made public by RINA.

In this case the Organisation shall return the withdrawn certificate to RINA and cannot use said certificate (certificate number, RINA id code, etc.) on the manufacturer's declaration of conformity for CE marking of the machine and on any other document.

If an Organisation, following the withdrawal of its certificate, intends to apply for certification again, it must submit a new application according to the entire procedure described in these Rules.

CHAPTER 7- RENUNCIATION

7.1 – Renunciation by the manufacturer

The Organisation can submit a request to RINA to renounce its certification for some certified machines for example if they are no longer produced/used.

In this case the Organisation shall return the relevant certificate to RINA.

When receiving a renunciation request, RINA updates the lists of certificates as per chapter 8 and informs the competent Administrations (notifying Authority, other notified Bodies, European Commission) that the certificate in question is no longer valid, prescribing, if the case, any actions that the Organisation shall take with regard to manufactured machines.

Starting from the renunciation request date, the Organisation cannot use RINA certificate (certificate number, RINA id code, etc.) on the manufacturer's declaration of conformity for CE marking of the machine and on any other document.

CHAPTER 8 – PUBLICATION BY RINA

8.1 – Setup and keeping of lists

RINA keeps the list of issued certificates up to date; the list of certificates of the machines included in Annex IV of Directive 2006/42/EC must contain at least the following information:

- certificate number;
- date of issue of the certificate;
- certification procedure adopted;
- name and address of the Organisation or its authorized representative established in the Community and production site;
- machine id data (type, model, application, etc.).

This list is updated not only when new certificates are issued but also in case of revision, suspension or withdrawal of previously existing certificates.

CHAPTER 9 – USE OF RINA CERTIFICATES

9.1 – Advertising, use of the logo

The Organization shall refer to the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION RC/C 17" on WEB site www.rina.org.

9.2 – Use of RINA certificate for CE marking of machines

In the presence of a valid RINA certificate, the Organisation shall affix, on the declaration of conformity for CE marking of a machine, all information required by the reference standards.

In case of Total Quality Guarantee certification (Annex X), the Organization affixes the RINA 0474 identification number on the marking plates of the machines covered by certification issued by RINA. This number must be affixed in accordance with the provisions of the directive.

When using the certificate, the Organisation shall prevent the obtained certificate from being deemed to be extended to other machines not covered by RINA certification.

CHAPTER 10 – CONTRACTUAL CONDITIONS

For contractual conditions reference shall be made to the requirements of RINA Rules “GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT, PERSONNEL AND INSPECTION CERTIFICATION RC/C 17” on WEB site www.rina.org.

RINA
Via Corsica, 12 - 16128 Genova - Italy
Tel. +39 01053851 - Fax: +39 0105351000
www.rina.org

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