Rules for Conformity Assessment of Medical Devices according to Directive 93/42/EEC

(transposed by Italian legislative decree n° 46/97)

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RINA SERVICES

classification, certification, inspection & testing

Contents

1. GENERAL

1.1 Aim and field of application

These Rules establish the requirements applied by RINA Services S.p.A. (in the following RINA) to verify compliance (certification) of medical devices with what is stated in Directive 93/42/EEC and subsequent amendments and integrations, as per Italian legislative decree n° 46 dated 24 February 1997, which transposes this Directive. These Rules also establish how certification may be requested, obtained, maintained and used, as well as its possible amendment, suspension, renouncement, reinstatement and withdrawal.

These Rules apply to the product types for which RINA is authorised to act according to the "Autorizzazione al rilascio della certificazione CE di rispondenza della conformità di dispositivi medici" issued by the Competent Authority.

1.2 Access to certification

All organisations legally set up according to the rules of the State they belong to and to any other applicable rules can access certification.

RINA may legitimately refuse certification requests from organisations subject to, or whose production or activities are subject to restriction, suspension or proscription by a public authority.

If RINA refuses the request, it will inform the applicant organisation in writing.

1.3 Confidentiality

The information acquired during the certification process will be considered and treated as confidential.

1.4 Participation of personnel appointed by the designating Authority as observers of the assessment activities

The designating Authorities, in connection with the procedures for the issue and maintenance of notification in favour of RINA, as body authorised to verify compliance according to the above-mentioned Community Directive and related legislative decree which transposes it, can request their observers to participate in the audits performed by RINA, in order to verify that the assessment methods adopted meet the applicable rules. The organisation will be informed in advance of this above request.

Should the organisation refuse the above request, the validity of the certificate will be suspended.

1.5 Delegation of part of the assessment activities

RINA reserves the right to delegate to others (for example laboratories and external collaborators) the performance of part of the assessment activities, analyses or tests, but retains overall responsibility.

2. DEFINITIONS

Accessory: an article which, whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

Competent Authority: the authority or authorities appointed to supervise the market and/or surveillance of devices.

Designating Authority: the authority or authorities appointed by a Member State to assess,, designate, notify and monitor notified bodies according to Directive 93/42/EEC.

CE certificate: document through which a third party (Notified Body) certifies that it has carried out an assessment process of the compliance of a medical device with the applicable requirements of the reference directive. In the following, a detailed explanation of the structure and content of the various types of certificates issued by Notified Bodies will be given.

Intended purpose: the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

Declaration of Conformity: document through which a manufacturer guarantees and declares that his/her products meet the applicable requirements of the reference directive.

Medical Device: any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or of compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Manufacturer: the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

Audit team: personnel appointed by RINA to perform conformity assessment.

Placing on the market: the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.

Authorised representative: any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community

instead of the manufacturer with regard to the latter's obligations under this Directive.

Putting into service: the stage at which a device has been made available to the final user as being ready for use on the Community market for the first time for its intended purpose.

Own Brand Labeller (OBL): OBL manufacturer means whoever affixes own brand label on a medical device already CE marked by another manufacturer (Original Equipment Manufacturer, OEM), to then place it on the market under own name.

3. LEGISLATION AND REFERENCE STANDARDS

The manufacturer (in the following also called "Organisation"), in order to be certified, is to comply with all the requirements of the applicable legislation, of these Rules and, in particular:

- Directive 93/42/EEC dated 14 June 1993 – OJ L 169 dated 12/7/1993 concerning medical devices and subsequent amendments and integrations.
- Italian legislative decree n° 46 dated 24 February 1997, "Attuazione della direttiva 93/42/CEE, concernente i dispositivi medici".
- Any guidelines, decrees, circulars technical specifications or other documents applicable to the medical devices subject to assessment.

4. CONFORMITY ASSESSMENT OF MEDICAL DEVICES

The certification procedures relevant to Annexes II and V of Directive 93/42/EEC are described in this chapter and, in particular:

- Full quality assurance system (Annex II Directive – module H);

- Production quality assurance (Annex V Directive – module D).

4.1 Application for certification

At the request of the manufacturer or of his authorised representative, who intends to request certification, RINA will send the form "INFORMATIVE QUESTIONNAIRE FOR OFFER" (*FORM-SYS01-CE MARK-01*) and a copy of these Rules.

The *FORM-SYS01-CE MARK-01* is to be returned to RINA, with all the applicable fields filled in and, in particular, is to contain the following information:

- name and address of the manufacturer or of his authorised representative established in the Community;
- essential characteristics of the product;
- conformity assessment procedure the organisation intends to adopt;
- any certification obtained for own Quality Management System (i.e.: UNI EN ISO 9001, EN ISO 13485:2012);
- declaration that the same application request has not been lodged with another Notified Body.

On receipt of the application (*FORM-SYS01-CE MARK-01*), duly filled in, and having made any further inquiries, where necessary, relating to the characteristics of the organisation and the devices in question, RINA will submit its technical-economic offer to the organisation.

The organisation can formally accept the offer by signing the "Certification request" form enclosed with the offer.

On receipt of the "Certification request", duly filled in and signed as acceptance of the offer, the certification process will begin and will be carried out in compliance with the RINA procedures and with these Rules.

RINA will inform the organisation of the contact person for certification (Program Administrator, PA) who, having made the necessary contact with the organisation, will start the assessment process by communicating the phases, programmes and time frame, as well as the name(s) of the auditor(s) who will perform the required audits at the organisation's sites.

With reference to the auditors appointed to carry out the assessment activities, the organisation may, for justified reasons, object to their appointment by providing written evidence.

4.2 Examination of the technical documentation

Together with acceptance of the offer or later, the organisation is to send RINA a copy of the technical documentation containing what is stated in Annex VII point 3 of the Directive.

The documentation will be examined at the RINA offices by a competent auditor appointed by RINA and communicated in advance to the organisation.

In the case of specific agreements with the organisation, part of the technical documentation may be checked at the organisation's offices.

The technical documentation will be assessed on the basis of the requirements of Directive 93/42/EEC and applicable reference standards.

The outcome of the examination of the technical documentation will be formally communicated to the organisation; any nonconformities found will have to be resolved by the organisation before the certification process can continue.

The positive outcome of the examination of the technical documentation is a necessary condition for the certification process to continue.

4.3 Quality System assessment

The manufacturer who has chosen the compliance path according to Annex II or Annex V will be required to implement a quality system as follows.

4.3.1 ANNEX II: Conformity based on full quality assurance

The manufacturer must ensure application of the quality system approved for the design, manufacture and final inspection of the product concerned. This system will be subject to audit by RINA and to surveillance in order to maintain certification.

The Quality System documentation is to include an adequate description of:

- the quality objectives;
- the organisational structure;
- the management responsibilities related to quality of design and products;
- the design specifications, including the standards which will be applied and the solutions adopted to fulfil the essential requirements of safety and health protection established by the Directive;
- the techniques, processes and systematic measures which will be used for the manufacture, in quality control and quality assurance;

- the tests and trials which will be carried out before, during and after manufacture and the frequency with which they will take place;
- the quality documentation, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned;
- the methods of monitoring achievement of the desired quality of design and product and the efficient operation of the quality assurance system.

The assessment procedure will include an inspection of the manufacturer's premises and, where considered necessary, of critical subcontractors or suppliers.

The outcome of the quality assurance system inspection will be notified to the manufacturer or to his authorised representative. It will contain the conclusions of the inspection and a reasoned assessment.

4.3.2 ANNEX V: Conformity based on production quality assurance

The manufacturer must ensure application of the quality system approved for the manufacture of the products concerned and carry out the final inspection. This system will be subject to inspection by RINA and to the pertinent surveillance audits in order to maintain certification.

The Quality System documentation is to include an adequate description of:

- the quality objectives,
- the organisational structure,
- the responsibilities of the managerial staff and their organisational authority where manufacture of the products is concerned;
- the techniques, processes and systematic measures applied to the relative production, monitoring and quality assurance processes;
- the appropriate tests and trials which will be carried out before, during and after manufacture and the frequency with which they will take place;
- the quality documentation, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned;
- the methods used to monitor achievement of the desired quality of product and efficient operation of the quality system.

The assessment procedure will include an inspection of the manufacturer's premises and, where considered necessary, of critical subcontractors or suppliers.

The outcome of the quality assurance system inspection will be notified to the manufacturer or to his authorised representative. It will contain the conclusions of the inspection and a reasoned assessment.

5. DESCRIPTION OF THE AUDIT ACTIVITIES

5.1 Audit activities for the purpose of issuing the certificate

RINA will also perform an audit of the organisation, communicating in advance the names of the audit team members, to check correct implementation of all the applicable procedures related to the construction and control of the medical devices assessed during the document review phase.

The audit activities consist of:

- a first certification audit, involving two stages and, following the successful outcome, issue of the certificate;
- subsequent surveillance and recertification audits;
- any additional audits and/or unannounced inspections during the three-year validity of the certificate.

The audit will consist in checking compliance of the product with the applicable essential requirements (Annex I of the Directive) and compliance of the organisation's Quality Management System with the requirements of the selected Annex, II or V.

At the end of the audit, the audit team will inform the organisation of any nonconformities found due to non-compliance with the applicable requirements.

At the time of the first certification audit, the organisation will be required to demonstrate that the system is fully operational and has been implemented for at least three months.

To ensure the audits are carried out effectively, the organisation is to guarantee the RINA auditors free access to its sites, production centres, to the personnel concerned and to the relevant documentation, as well as providing the necessary assistance as regards safety and the complete carrying out of the audit.

5.2 Audit report

At the end of the audit, the organisation will be given an audit report containing, among others, any nonconformities found and recommendations, as well as the outcome of any analyses and tests of processes and/or products.

On the same occasion, the organisation will have the possibility, in a specific part of the report, to make any observations or express its reservations concerning the findings identified.

Three working days after the report has been given to the organisation and, in the absence of any written communication from RINA, the audit report will be considered as confirmed.

After analysing the causes of any nonconformities found, the organisation will be required to propose the necessary corrective action and time frame for implementation to RINA by the date established in the report.

In the case of type A findings (see paragraph 7), or of other findings whose number, in the opinion of the audit team, is such as to compromise the proper functioning of the system, the certification process will be suspended.

In such cases, within three months of the audit date, RINA may perform a supplementary audit to check proper implementation of the corrective action proposed; following the positive outcome, the certification process will restart.

If the above period is exceeded, the organisation's system will be subject to a complete review within six months of the date of the finding.

If, at the end of this six month period, the audit has not been successfully completed, RINA will consider the certification file closed and charge the time and expenses incurred up till then.

In such cases, if the organisation intends to pursue certification, it will have to submit a new request and repeat the certification process. The above time limits may, in special cases, be modified, in the opinion of RINA, if the organisation's request is justified.

5.3 Completion of the certification activities

Following the successful outcome of the audit and subject to the favourable opinion of the RINA Medical Devices Technical Committee, the CE certificate will be issued.

Provided the outcome of the annual maintenance audits is positive during the two years following the certification audit, the certificate remains valid.

6. MAINTENANCE OF CERTIFICATION

6.1 Surveillance audit

In order to maintain certification, surveillance audits will be carried out at least once a year in relation to the date of issue of the certificate.

The frequency of these audits will be planned following the outcome of the first certification audit and the method used will be similar to that adopted for the first certification audit.

The surveillance plan may be modified by RINA on the basis of the results of each audit.

Any variations in the above audit plan, for justified reasons, are to be agreed in advance with RINA.

The dates of the surveillance audits will be agreed with the organisation in due time and confirmed in writing with the names of the RINA audit team members.

In the case of major nonconformities or of other findings whose number, in the opinion of the audit team, is such as to compromise the effectiveness of the system, the organisation will be subject to a supplementary audit, within a time frame determined by RINA and, in any case, not more than three months after the end of the surveillance audit, aimed at checking the effectiveness of the corrections and corrective action proposed.

If the nonconformities are not resolved by the established deadline or they are such as not to ensure compliance of the supplied product with the applicable rules, RINA may suspend the certificate until they have been remedied.

6.2 Recertification

Within three years of the date of issue of the certificate and, in any case, in time for it to be reissued to maintain coverage of the certified products, a recertification audit will be performed covering the entire system and products.

The method used for the recertification audit will be similar to that adopted for the first certification audit.

6.3 Unannounced audits

In particular cases, RINA may carry out unannounced audits at the organisation, which will be performed according to the above-mentioned auditing procedures.

7. FINDINGS

Findings related to the subject of certification are divided into the following types:

a) Type A findings (major nonconformities):

- non-compliance with one or more requirements of the reference standards;
- a situation which could lead to the delivery of a product which does not meet the requirements of the Directive or does not comply with the legislation in force in the Member State where the product is placed on the market;

- non-compliance with one or more requirements of these Rules;
- a situation such as to cause a serious shortcoming in the system or to reduce its ability to ensure control of the product subject to marking.

b) Type B findings (secondary deficiencies or minor nonconformities):

- a non-conforming situation which, in the opinion of the RINA audit team, based on its experience, is such as not to lead to a serious deficiency in the system and not to reduce its ability to ensure product control.

c) Type C findings (recommendations, observations):

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

8. CHANGES TO CERTIFICATION

During the period of validity of the certificate, the manufacturer or his/her authorised representative is to inform RINA of any project to update or modify the system and of any integration and/or modification related to the products subject to marking.

RINA, in relation to the characteristics and nature of these modifications/integrations, will assess whether it is necessary to perform an additional document review and/or on-site assessment and will inform the organisation accordingly.

In the case of a change in company name, the organisation is to inform RINA of the changes made by sending the following documentation:

- copy of the new certificate of registration with the Chamber of Commerce or equivalent document,
- copy of the notarial act affirming this change.

Having made the necessary checks, RINA will issue a new certificate which annuls and replaces the previous one.

Any changes made by RINA to its requirements to obtain and maintain certification, for example following the issue of new regulatory requirements, will be notified to all companies certified by RINA. These companies will be required to comply with the new provisions.

In relation to the above notification to the certified organisations of changes to its requirements, RINA will:

- take into account any comments they may have in this connection;
- specify and notify to the organisations the date of entry into force of the changes, the terms of the transition and any alignment required;
- check, where necessary, compliance and suitability of the measures taken by the organisations to meet the new requirements, also through supplementary audits which will be charged to the organisations.

The organisation is responsible for keeping the documentation sent by RINA up to date, eliminating obsolete documents.

If the organisation does not comply with the new requirements by the agreed date, this could lead to suspension or withdrawal of the certificate.

If the organisation does not accept the new requirements, the relative certificate will be

renounced/suspended/withdrawn as stated in chapter 12.

8.1 Certificate transfer

There are two cases in which certificate transfer is possible:

1. "Voluntary" change, with termination of the contract with the previous Notified Body;
2. "Involuntary/compulsory" change due to breakdown of the Notified Body.

In both cases, the manufacturer and the previous Body are to agree on the date until which the medical devices can be placed on the market according to the contractual terms and conditions of the previous Body.

In such cases, PA is to record the following information:

- date of invalidity of the current certificates, (the certificates are valid for the medical devices which have already been produced);
- date when the placing on the market of the above devices was completed;
- copy of the communication from the manufacturer to the competent authorities concerning change of Body;
- definition of the transition period (which is not to exceed 6 months) for use of the old labels and promotional material. Changes to the label of the device are to be documented with reference to a specific batch or production number which the new label will contain.

The contract between RINA and the manufacturer and the conformity assessment procedure will be managed in the same way as established and illustrated in these Rules.

9. PUBLICATION BY RINA

RINA keeps an up-to-date list of the certificates issued with the following information:

- certificate number;
- date of issue of the certificate;
- procedure adopted for certification;
- name and address of the organisation or of its authorised representative designated in the European Union and production location;
- identification of the medical device (type, model, intended use, etc.).

The list will be kept up to date in relation to new certificates issued as well as any revision, suspension or withdrawal of pre-existing certificates.

10. ADVERTISING - USE FOR CE MARKING PURPOSES

10.1 Advertising certification

An organisation can advertise the fact that it has obtained RINA certification any way it likes.

However, it is to clearly indicate any limitations and conditions imposed by RINA at the time of issue of the certificate.

The organisation can reproduce the certificate in full, enlarging or reducing it, provided it remains legible and is not altered in any way.

10.2 Use of medical devices for the purpose of CE marking

Once the organisation has obtained valid CE certification from RINA, it is to include, on the conformity declaration for the purpose of CE marking of the medical device, all the information required by the reference legislative provisions.

In connection with the certificate, the organisation is to avoid any misunderstanding that certification could be intended as covering other medical devices not within the scope of certification issued by RINA.

11. OBLIGATIONS OF THE MANUFACTURER AS REGARDS DOCUMENTATION

The manufacturer or his authorised representative is to keep at the disposal of the national authorities, for at least five years after the last product has been manufactured and in the case of implantable devices, for at least fifteen years: the technical documentation and the quality system documentation; the decisions and inspection and test reports carried out following RINA checks and assessments.

12. SUSPENSION, RENOUNCEMENT, REINSTATEMENT AND WITHDRAWAL OF CERTIFICATES

12.1 Suspension

The validity of the certificate issued may be suspended in accordance with the "General contract conditions governing system, product and personnel certification" and in the following cases:

- if the organisation does not allow the programmed surveillance audits to be carried out when due;
- if major nonconformities are found during the audits which have not been resolved by the deadline established by RINA;
- if the organisation does not meet the deadline established by RINA to communicate the corrective action related to the nonconformities reported in the audit report;
- if the organisation has made changes to the system which have not been accepted by RINA;
- in the case of important company restructuring which RINA has not been informed about;
- if the organisation refuses or hinders the participation in any audit of observers from the competent authorities;
- if the organisation is in arrears as regards payment of RINA services;
- any justified and serious complaints received by RINA;
- if the organisation has misused the RINA identification data to be given on the manufacturer's conformity declaration for the purpose of CE product marking and/or the certificate issued by RINA and has not implemented the measures required by RINA;
- following evidence of non-compliance with the mandatory laws and regulations applicable to the product;

- in any other case which, in the opinion of RINA, could negatively influence control of the system.

The organisation can also ask RINA, for justified reasons, to suspend its certificate for a maximum period, in general, of not more than six months.

Suspension will be notified to the organisation in writing by registered letter, establishing the conditions for reinstatement of certification and the deadline for its implementation.

Suspension of the validity of the certificate may be made public by RINA, and in any case communicated to the competent authority.

During the suspension period, the organisation is not allowed to use RINA certification (certificate number, RINA identification, etc.) either on the manufacturer's declaration of conformity for the purpose of CE marking of the product in question or on any other document.

12.2 Reinstatement

Reinstatement of the certificate is dependent on a check to be made by RINA to verify that the deficiencies which led to suspension have been resolved; this will be done through an audit to ascertain that the control system complies with all the requirements of the reference standards.

Reinstatement will be notified to the organisation in writing by registered letter and made public by RINA, if notice of suspension was also made public at the time and, in any case, communicated to the competent authority.

12.3 Withdrawal

If the conditions in 12.2 are not met by the required deadline, the certificate will be revoked.

Withdrawal of the certificate may be decided in accordance with the "General contract conditions governing system, product and personnel certification" and in the following cases:

- when circumstances, such as those mentioned in 12.1 for suspension occur, which are considered particularly serious;
- if the organisation stops supplying the product subject to certification for a period, in general, of more than six months;
- persistent arrears in paying RINA for its services;
- if the organisation does not accept the new economic terms established by RINA for possible change to the contract;
- for any other serious reason, in the opinion of RINA.

Withdrawal of the certificate will be notified to the organisation in writing by registered letter. Withdrawal will be made public by RINA and, in any case, communicated to the competent authority.

The organisation whose certificate has been withdrawn is to return the certificate to RINA and is not allowed to use RINA certification (certificate number, RINA identification, etc.) either on the manufacturer's declaration of conformity for the purpose of CE marking of the product in question or on any other document.

Following withdrawal, if an organisation intends to request certification again, it will have to submit a new application and repeat the whole process.

12.4 Renouncement

An organisation may submit a request to RINA to renounce certification for some or all of its products for which it has obtained certification, for example because the products are no longer produced.

In such a case, the organisation is to return the pertinent certificate.

On receipt of the renouncement request, RINA will update the lists indicated in chapter 9 and, if appropriate, also prescribe any action the organisation is to take for the products already manufactured.

From the date of the renouncement request, the organisation will not be allowed to use RINA certification (certificate number, RINA identification, etc.) either on the manufacturer's declaration of conformity for the purpose of CE marking of the product in question or on any other document.

Renouncement of the certificate will be notified to the organisation in writing by registered letter. Renouncement will be communicated to the competent authority.

13. CE certification on the basis of an OBL (Own Brand Labelling) contract

The European Union contemplates the possibility that own brand labellers assume the role of manufacturer according to Directive 93/42/EEC, stipulating specific contracts called "Own Brand Labelling" (OBL) with manufacturers (in the following called "OEM") whose system has obtained approval to affix CE marking.

In such a case, the organisation is to provide RINA with the following documentation:

- a copy of the contract with the OEM supplier;
- a copy of the OEM supplier's CE certificate;
- a copy of the OEM supplier's labels and instructions for use;
- declaration of identicalness with the product variants of the OEM manufacturer;
- the OEM manufacturer's technical documentation which is to comply with the requirements of Directive 93/42/EEC;
- Quality System documentation.

The aim of the conformity audit of the OBL manufacturer is to check that:

- the CE certification obtained by the OEM supplier is valid;
- the medical device subject to certification is identical to the one that the supplier places on the market under his/her own name, with CE marking, in his/her role as manufacturer pursuant to Directive 93/42/EEC;
- the quality system implemented complies with the requirements of the Annex of Directive 93/42/EEC chosen by the manufacturer to assess conformity of the medical device.

14. CONTRACTUAL CONDITIONS

With reference to the contractual conditions, the requirements of the current edition of the RINA "General contract conditions governing system, product and personnel certification", apply. This document is available from the site www.rina.org.

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