Supplementary appendix – Reference standard: ISO 13485

Edition: May 2025

CHAPTER 1 - GENERAL

This supplementary appendix defines the additional and/or substitutive procedures applied by RINA for the certification of ISO 13485 Management Systems in relation to the requirements of the Rules for the Certification of Management Systems RC/C40

CHAPTER 2 - REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

According to what is stated in the General Rules for the Certification of Management Systems RC/C40, to obtain RINA certification a Quality Management System must first and henceforth satisfy the requirements of ISO 13485 and the additional requirements of accreditation bodies (such as: ACCREDIA Letter, IAF MD08, IAF MD09).

CHAPTER 3 - INITIAL CERTIFICATION

3.1

As well as what is established in the General Rules for the Certification of Management Systems, an organisation must inform RINA of:

- the role(s) undertaken by the organization under the applicable regulatory requirements (manufacturer, authorized representative, importer, distributor, services supplier, etc…);
- any requirement of the standard is excluded/not applicable and the related justifications;
- any outsourced process that can affect product conformity to standard requirements;
- type of products falling within the certification scope (name, description, intended use of products, risk class of devices, if the devices are sterile and the sterilization method);
- in case of suppliers or other external parties providing parts which are not categorized as finished medical devices1, the specific description of the performed activities (e.g. raw materials and/or components and/or subassemblies, calibration services, distribution services, maintenance services, distribution services, transportation services, Consulting services related to medical devices, packaging services, etc…).

[1] A finished medical device is defined as any device or accessory to any medical device that is suitable for use or capable of functioning, whether or not it is packaged, labelled, or sterilized.

3.4

As well as what is established in the General Rules for the Certification of Management Systems, an organisation must provide to RINA at least the following documentation:

- a Quality Manual (last valid revision) that includes:
    - the scope of the quality management system, including details of and justification for any exclusion or non-application;
    - the documented procedures for the quality management system, or reference to them;
    - a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

- documented procedures and records required by the standard;
- documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;
- other documentation specified by applicable regulatory requirements (ex. Any certification issued by Notified Body or Authority for the trading of the medical devices).

3.5
Where higher risk medical devices (e.g. GHTF C and D, C: Medium High Risk, D: High Risk (see IAF Medical Device Nomenclature Including Medical Device Risk Classifications - IAF ID 13).) are concerned, the stage 1 should be performed on-site.

CHAPTER 4 - MAINTENANCE OF CERTIFICATION

4.2
As well as what is stated in the General Rules for the Certification of Management Systems, the surveillance programme shall include a review of actions taken for notification of adverse events, advisory notices, and recalls.
4.4
As well as what is stated in the General Rules for the Certification of Management Systems, RINA may be required SHORT-NOTICE AUDIT or UNANNOUNCED AUDIT when:

- external factors apply such as:
  - available post-market surveillance data known to RINA on the subject devices indicate a possible significant deficiency in the quality management system;
  - significant safety related information becoming known to RINA.
- significant changes occur which have been submitted as required by the regulations or become known to RINA, and which could affect the decision on the client's state of compliance with the regulatory requirements.

An unannounced o short-notice audit can be required if RINA has valid reasons for the implementation of corrective actions or compliance with regulatory standards and requirements.

CHAPTER 5 - RECERTIFICATION

The requirements of the RINA Rules for the certification of management systems (RC/C 40) apply.

CHAPTER 6 - CONDUCTION OF AUDITS

6.1.3
As well as what is stated in the General Rules for the Certification of Management Systems, examples of non-conformities are:

i. failure to address applicable requirements for quality management systems (e.g. failure to have a complaint handling or training system);
ii. failure to implement applicable requirements for quality management systems;
iii. failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects;
iv. products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling;
v. the existence of products which clearly do not comply with the client's specifications and/or the regulatory requirements;
vi. repeated nonconformities from previous audits.

CHAPTER 7 - MANAGEMENT OF CERTIFICATES OF CONFORMITY

The requirements of the RINA Rules for the certification of management systems (RC/C 40) apply.

CHAPTER 8 - MODIFICATION OF CERTIFICATION AND COMMUNICATION OF CHANGES

The requirements of the RINA Rules for the certification of management systems (RC/C 40) and of the "GENERAL CONTRACT CONDITIONS FOR CONFORMITY ASSESSMENT ACTIVITIES" apply.

CHAPTER 9 - SPECIAL REQUIREMENTS FOR MULTI-SITE ORGANISATIONS

9.1

As well as what is stated in the General Rules for the Certification of Management Systems, sites involved in design, development and manufacturing of medical devices (TA A.1.1-1.6) cannot be sampled.

CHAPTER 10 - TRANSFER OF ACCREDITED CERTIFICATES

The requirements of the RINA Rules for the certification of management systems (RC/C 40) apply.

CHAPTER 11 - SUSPENSION, REINSTATEMENT AND WITHDRAWAL OF CERTIFICATION

11.1

As well as what is stated in the RINA Rules for the certification of management systems (RC/C 40) and in the "GENERAL CONTRACT CONDITIONS FOR CONFORMITY ASSESSMENT ACTIVITIES", the validity of the certificate of conformity is suspended in case of RINA's evaluation about serious incident, or a breach of regulation necessitating the involvement of the appropriate regulatory authority, if it has been demonstrated that the system seriously failed to meet the certification requirements.

CHAPTER 12 - RENUNCIATION OF CERTIFICATION

The requirements of the RINA Rules for the certification of management systems (RC/C 40) apply.

CHAPTER 13 - CONTRACTUAL CONDITIONS

The requirements of the RINA Rules for the certification of management systems (RC/C 40) and of the "GENERAL CONTRACT CONDITIONS FOR CONFORMITY ASSESSMENT ACTIVITIES" apply.