Rules for the certification of Quality Management Systems in the Medical Devices sector

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Technical rules

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CHAPTER 1
GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Quality Management Systems in the Medical Devices sector in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made

1.2

RINA issues certification in accordance with the requirements of the ISO/IEC 17021-1:2015 Standard to organizations whose Management System has been recognized as fully conforming to all the requirements of the ISO 13485:2016.

CHAPTER 2
REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

According to what is stated in the General Rules for the Certification of Management Systems, 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.

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 devices[1], 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…).

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:
    a. the scope of the quality management system, including details of and justification for any exclusion or non-application;
    b. the documented procedures for the quality management system, or reference to them;
    c. 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[2]) are concerned, the stage 1 should be performed on-site.

[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.

[2] C: Medium High Risk, D: High Risk
(see IAF Medical Device Nomenclature Including Medical Device Risk Classifications - IAF ID 13).

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 6

PERFORMANCE 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 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 11

SUSPENSION, REINSTATEMENT AND WITHDRAWAL OF CERTIFICATION

11.1

As well as what is stated in the General Rules for the Certification of Management Systems, 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.

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