



RINA certification

infrastructures and constructions
health and food
manufacturing
territory and administration
services
transport and logistics

ISO 13485 Medical Devices

Quality management systems Requirements for regulatory purposes

What it is

ISO 13485 "Medical Devices – Quality management systems – Requirements for regulatory purposes" is a **voluntary standard** for the certification of quality management systems for organisations which design, develop, produce, market, install and service medical devices.

The standard was published on 15 July 2003.

Objectives

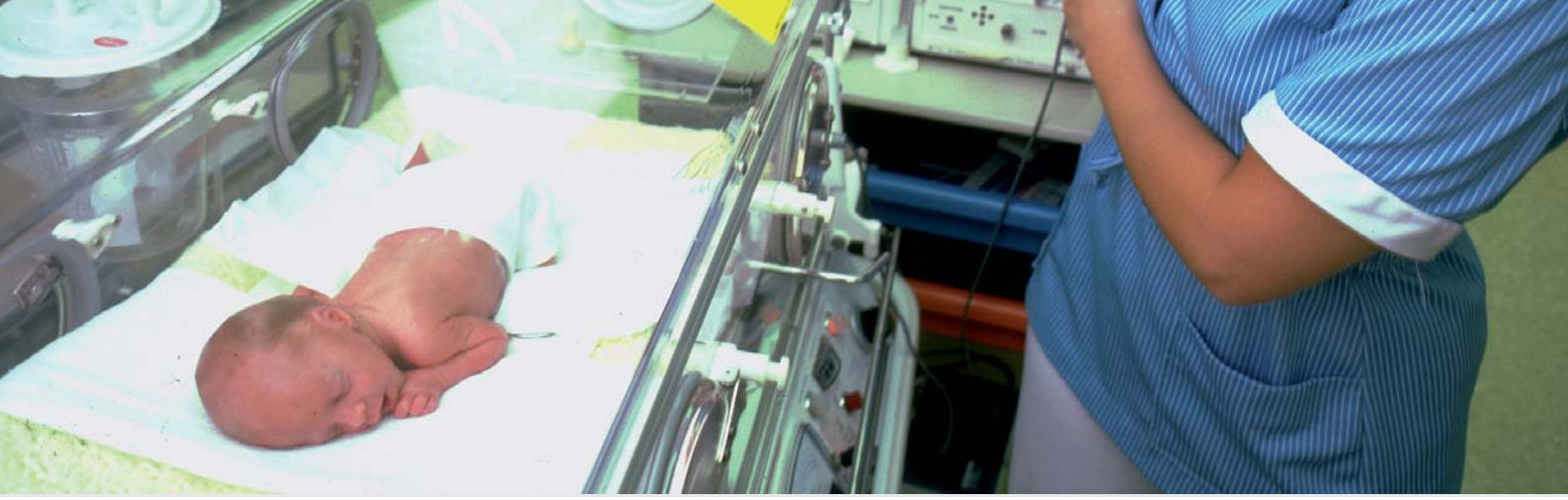
- Provide a means to develop quality management systems applied to organisations in the medical devices sector, **in compliance with regulatory requirements**.
- In particular, for organisations which intend to market their products within the European Union, RINA certification focuses on appropriate **risk analysis and management** associated with the use of the device, in line with European legislation.

Key points

- **Risk analysis**, developed through an identification, assessment, prevention and assessment of residual risk approach;
- **Communication – information** to the user;
- Management of the **non conforming device** from the point of view of certain traceability of the product and of its critical components;
- **Company management system**;
- **Process control**.

More detailed information can be found at the following site www.rina.org or info@rina.org
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Strong points

- Completion and adaptation of the **ISO 9001 requirements to the pertinent specification for Medical Devices**
- Integrability with other management systems
- Adds value and greater prominence to the **system elements required for CE Marking purposes**
- Creates a **guarantee for the management**

Quality and Medical Devices

Certification

RINA, principal Italian Certification Body, has the necessary competency and professionalism to offer its clientele:

- **Pre – audit and gap analysis referred to the ISO 13485 standard**
- **ISO 13485 certification**

Moreover, through RTF – the **RINA Training Factory**, the following courses are available to the clientele:

- **Training courses on the standard.**



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RINA: an international role

RINA has always played an active role within the most authoritative organisations of the sector, such as UNI, CEI and ISO to draw up rules and regulations and the CISQ Federation, through which it adheres to the IQNet agreement, for the mutual recognition of certificates internationally.

RINA has a widespread organised technical-commercial structure in Italy and abroad so as to ensure specific and timely services, ready to meet its clients' most varied and precise needs.



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