Swiss Association
for Quality and Management
Systems (SQS)

Directive 93/42/EEC and EN ISO 13485:2012

Certification of the quality management systems of medical device manufacturers

Incentive

The conformity of medical devices must be assessed under Directive 93/42/EEC before they are brought to market. When it comes to the required verification of conformity, the preferred approach is to arrange for a Conformity Assessment Body (CAB) or Notified Body (NB) to certify the QM systems as conforming to ISO 9001 and/or to EN ISO 13485. A positive assessment leads to authorisation to use the CE mark and to place medical devices on the market.
The manufacturer must provide evidence of the conformity of the device with the fundamental requirements set out in the directive and in the harmonised standards.

Outcome

The general concern is the manufacture of safe and high-quality medical devices. Manufacturers of medical devices are required to set up and maintain a quality control system and, where applicable, to have it certified on the basis of a table of conformity assessment criteria.

Target groups

Industrial undertakings and service enterprises working in the field of medical devices.

Validity

3 years – there is an annual audit to ensure that standards are being maintained and a recertification audit after 3 years.

Swiss Made

Partner of IQNet

Recognition

SQS is registered as a Notified Body under number 1250.
The SQS certificate of conformity with Directive 93/42/EEC has international validity.
The SQS certificate of conformity with EN ISO 13485 has international validity and is recognised through partnership with IQNet.

Combinations

EN ISO 13485 is compatible with ISO 9001 (quality management), ISO 14001 (environmental management) and OHSAS 18001 (occupational health and safety).

Contact

Further general information can be obtained from our office in Zollikofen.

Our auditors are also available to answer queries on specific subjects.

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