



CERTIFICATION OF THE QM SYSTEMS OF MEDICAL DEVICE MANU- FACTURERS CE 1250



BACKGROUND

Why certification?

The conformity of medical devices and in-vitro diagnostic medication with the EU Directives 93/42/EEC, 90/385/EEC and 98/79/EEC must be evaluated before the devices are marketed for sale. The preferred method for verifying conformity is the certification of the QM systems in accordance with ISO 9001 and/or ISO 13485 by a **Conformity Assessment Body CAB, Notified Body NB**. The result of the positive assessment means the authorisation to use the CE label and to market medical devices.

AIMS

What are the intended aims?

For the manufacturer to demonstrate compliance (conformity) of the device with the fundamental requirements of the Directives and the harmonised standards.

TARGET GROUPS

Who are the intended target groups?

Manufacturers of

- medical devices,
- medical devices for active implantation,
- in-vitro diagnostic medication.

PROCEDURE

What does it involve?

The task is to create safe, high quality medical devices. Manufacturers of medical devices must develop and maintain a quality assurance system and, if necessary, have this certificated by a Conformity Assessment Body.

QUALITY CRITERIA

What is required?

The core elements of the Directives are:

- adherence to the fundamental requirements,
- ascertaining, evaluating and minimising risks for patients, users and third parties (risk analysis),
- documentation of the development,
- guaranteeing the effectiveness and safety.

The conformity assessment procedure, compulsory reporting and other requirements depend upon the devices risk potential. Every manufacturer or marketing company has to classify and assess their devices.

INFORMATION

I'd like to know more!

Further information and requirements can be obtained via the SQS branch or via our expert auditors.

CERTIFICATE/RECOGNITION

ISO certificates and EC certificates

- can only be issued by accredited certification institutions/Conformity Assessment Body,
- are valid for 3 years, after which re-certification is carried out – in the sense of continual further development.

PROFILE

Who is SQS?

SQS is your competent contact partner for the certification of medical device manufacturers' QM systems

The Swiss Association for Quality and Management Systems

- is an independent, non-profit organisation,
- is accredited as a certification body by the SAS (Swiss Accreditation Service),
- provides certification for, amongst others, quality management systems in accordance with ISO 9001, as well as environmental management systems in accordance with ISO 14001,
- provides certification in the field of medical devices: QM systems in accordance with ISO 9001, ISO 13485, Directives 93/42/EEC and 90/385/EEC,
- has expert, trained auditors with experience in the sector,
- is named as Conformity Assessment Body (CAB, NB) with identification number CE 1250 by Swissmedic,
- is in the accreditation process of in-vitro diagnostic medication.

REGISTRATION

Where can I register?

Contact us at:

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