# Certification of Quality Management Systems according to EN ISO 13485:2016 for medical devices

## EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes

CERTIFICATION ACCORDING TO EN ISO 13485 : 2016

### Certification of Quality Management Systems according to EN ISO 13485:2016 or ISO 13485:2016 for medical devices



### EN ISO 13485:2016 - Medical devices - Quality management systems - Requirements for regulatory purposes

The Czech Office for Standards, Metrology and Testing promulgated the standard EN ISO 13485:2016 as harmonized with the European directives 93/42/EEC, 90/385/EEC and 98/79/EC which permits their use for demonstration of conformity with requirements of the above European directives.

With respect to increased demands on quality management system of medical devices suppliers and manufacturers EN ISO 13485:2016 standard was elaborated. This standard contains criteria for the whole scope of the medical devices quality management system.

The certificate according to EN ISO 13485:2016 standard covers the whole system of management of the organisation manufacturing or supplying medical devices and appropriate services.

### Benefits of the quality management system certification according to EN ISO 13485:2016

- Demonstration of commitment to meet legal and regulation requirements;
- Guarantee of constancy of a production process and thus of a stable and high quality of services rendered and products supplied to customers;
- Demonstration of suitability, efficiency and effectiveness of the implemented quality management system by a third independent party;
- Increase in quality of the management system, improvement of the organisation's organisational structure;
- Improvement of order and an increase in effectiveness in the entire organisation;
- Optimisation of costs - reduction in operating costs, decrease in costs of non-conforming products, savings in raw-materials, energy and other resources;
- Increase in confidence of public and state control bodies in manufacturer of medical devices

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## Offer of CQS services

- Situation audits
- Certification audits (two-stepped), recertification audits
- Audits conducted in the English, German or Russian languages
- CQS certificates and IQNET international certificates

## Address

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## Contact persons

**Head of CQS certification body**
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can inform you about CQS certification procedures, certification terms and conditions and technical matters during certification

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can inform you about CQS certification procedures, administrative and organisational matters during certification

Company registration number (IČ): 69346305 Tax registration number (DIČ): CZ69346305

CQS is registered at the Municipal Court in Prague, file number L 58728