

# Benefits of ISO 13485 Certification



**ISO 13485:2016 - Medical devices — Quality Management System**

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In the medical device industry, quality and safety are not just expectations of customers and patients; it is an essential requirements of them. Organisations need to be very careful when they design, develop, and manufacture medical devices because even a small mistake can impact a patient's health or overall treatment. To avoid such risks and ensure safe manufacturing practices, many organisations implement [ISO 13485 Certification](#), which is an internationally recognised standard for Quality Management Systems in the medical device sector.

## What is ISO 13485?

ISO 13485 Certification is an international standard that defines the requirements for Quality Management System (QMS), specifically it is designed for companies that are involved in the medical device industry. It makes sure that organisations consistently design, produce, install, and deliver medical devices that are safe, reliable, and meet all regulatory requirements. Whether you are a manufacturer, supplier, distributor, or service provider in the medical device sector. This certification helps you to meet global expectations.

## Benefits of ISO 13485 Certification

**Better Quality Products** – It helps companies to build medical devices in a proper and controlled way, so that the organization can improve their products and make them in a high-quality manner.

**Builds Customer Trust** – When customers or hospitals see that your company is ISO certified, they feel more confident, which builds trust and also shows your customers and partners that you care about quality and safety.

**Reduce risk** – This standard focuses on identifying and controlling the risks throughout the product lifecycle.

**Improves Process Control** - This standard guides organisations to create clear procedures, maintain records, and monitor performance so that they can improve overall performance.

**Follow compliance** – With this certification, the organization can follow national and international regulations.

**Boosts Reputation** – Certification shows that your organisation's dedication to quality and safety.

**Global Recognition** – ISO 13485 is a globally recognised certification that helps companies to make their presence in the international markets, and also get new opportunities with international clients.

## Which Industry Can Get ISO 13485 Certification

Any organization that wants to improve its medical device can get this certification

- Medical device manufacturers
- Software Developers for Medical Devices
- Healthcare Service Providers
- Distributors & Retailers

- Component Suppliers

## Cost of ISO 13485 Certification

The cost of ISO 13485 Certification depends on various factors like:

- Size of your company
- Number of employees and locations
- Complexity of processes and products
- The certification body you choose

## Why Choose Us?

If you want to improve the quality of medical devices in the competitive market, then choose SQC Certification. We provide various ISO standards and help the organization to meet international quality standards. Our approach is to ensure you achieve certification smoothly. Along with that, you can also make a global presence in the international market and build trust with customers and partners.

### Contact us

- **Visit our website** [www.sqccertification.com](http://www.sqccertification.com)
- **Call us now at** 9910340648
- **Email-** [info@sqccertification.com](mailto:info@sqccertification.com)

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