Ultimate List of ISO Standards for Medical

The International Standardization Organization (ISO) is an independent, non-governmental organization that has created thousands of international standards for numerous industries, including medical devices. ISO standards are voluntary, consensus-based documents that provide guidance on particular aspects of technology and manufacturing.

For medical device manufacturers, ISO standards are critical not only to building high-quality medical devices, but to remaining compliant with regulatory requirements while doing so.

That's because many ISO standards are recognized by regulatory bodies such as the Food and Drug Administration (FDA) in the US, or have been harmonized with regulations in other parts of the world, such as the European Union.

So, even though ISO standards do not have the force of law, they are essential guides for medical device and in vitro diagnostic device companies.

Below, you'll find a list of the most searched for and widely applicable **ISO standards for medical devices**. While this list doesn't include *every* ISO standard that can apply to a given medical device or in vitro diagnostic device, it does include some of the most important standards for building safe and effective medical devices—all in one place.

Use this list to quickly and easily find up-to-date ISO standards that apply to your device. Happy scrolling!

FREE RESOURCE: Download our Ultimate List of ISO Standards for Medical Devices.

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No.	Standard	Name
1.	ISO 13485	*Medical devices — Quality management systems — Requirements for regulatory purposes*

2.	ISO 14971	*Medical devices — Application of risk management to medical devices*
3.	IEC 62304	*Medical device software — Software life cycle processes*
4.	ISO 62366-1	*Medical devices - Part 1: Application of usability engineering to medical devices*
5.	ISO 11135	*Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*
6.	ISO 15223-1	*Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*
7.	ISO 80369-1	*Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*
8.	ISO 11607-1	*Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*
9.	ISO 11607-2	*Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*
10.	ISO 11137-1	*Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
11.	ISO 14155	*Clinical investigation of medical devices for human subjects — Good clinical practice*

12.	**ISO 19001**	*In vitro diagnostic medical devices — Information supplied by the manufacturer with in vitro diagnostic reagents for staining in biology*
13.	**ISO/TR 24971**	*Medical devices — Guidance on the application of ISO 14971*
14.	**ISO 11737-2**	*Sterilization of healthcare products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilized product*
15.	**ISO 16571**	*Systems for evacuation of plume generated by medical devices*
16.	**ISO 20916**	*In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice*
17.	**IEC 80001-1**	*Safety, effectiveness and security in the implementation and use for connected medical devices or connected health software — Part 1: Application of risk management*
18.	**IEC/TR 80002-1**	*Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software*
19.	**IEC/TR 80002-2**	*Medical device software — Part 2: Validation of software for medical device quality systems*
20.	**IEC/TR 80002-3**	*Medical device software — Part 3: Process reference model of medical device software life cycle processes (IEC 62304)*
21.	**ISO 10993-1**	*Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

22.	ISO 10993-2	*Biological evaluation of medical devices — Part 2: Animal welfare requirements*
23.	ISO 10993-4	*Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*
24.	ISO 10993-5	*Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*
25.	ISO 27186	*Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements*
26.	ISO 15194	*In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*
27.	ISO 15883-1	*Washer Disinfectors — Part 1: General requirements, terms and definitions and tests*
28.	ISO 15883-2	*Washer Disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*
29.	ISO 15883-5	*Washer Disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*
30.	ISO 9626	*Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

31.	ISO 11117	*Gas cylinders — Valve protection caps and guards — Design, construction and tests*
32.	ISO 16142-1	*Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*
33.	ISO 16142-2	*Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*
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49.	ISO 20417	*Medical devices — Information to be supplied by the manufacturer*

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