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ISO Standards of Medical Devices

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Abstract

The medical device has become a decisive device in many instances. As there are more unsafe, the producer should bestow with an ideal medical device in phases of quality & safety. To produce a consistent device universally, there are some standards to be followed. Standards can cover a broad range of business and technology types, including IVDs and medical devices, and software that escort them. Standards are essential to maintain product compliance while synchronizing comparable requirements both nationally and internationally. For medical device industrialists, ISO standards derogatory not only making high-quality medical devices but enduring amenable to regulatory requirements while doing. For medical device companies, adherence to ISO medical device standards can lead to the elaboration of safer and more efficacious products that are more closely allied with user needs. In addition, attaining ISO correspondence certification is a required step in retrieving certain international marketplaces.

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Introduction

Definition

A medical device is "an instrument, apparatus, machine, contrivance, implants, in-vitro reagent, or other similar including a module par or accessory which is

- Comprehended in the official United States pharmacopoeia.
- Envisioned for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of diseases, in man or animals
- Intended to affect the function of the body of a man or animal, which does not achieve any chemical action within the body of animal or man which is not reliant upon being metabolized for the achievement of any of its primary intended purposes'' [1].
- Medical devices are subject to firm general controls and procedural regulations. The development and use of standards are necessary to ensure the safety and efficacy of medical devices.
- Various regulatory agencies and standards organizations co-operate to establish the accepted standards for medical equipment. Standard-setting activities include the development of performance characteristics, characterization and testing procedures, manufacturing practices, product standards, scientific etiquettes, acquiescence criteria, factor stipulations, labelling, or other technical or policy criteria [2].

Classification of Medical Devices

Medical devices are classified into classes based on control necessary to attain the safety, quality and effectiveness of the device. Classification of medical device depends on intended use, indication for use and the risk that a device enacts on the patient/user [6, 7, 8, 9, and 10].

Medical Device Classification in Different Countries

Countries	Medical Device Classification			
INDIA	Class-A	Class-B	Class-C	Class-D
USA	Class-I	Class-II	Class-III	-
EU	Class-I	Class-II-a, II-b	Class-III	-
CANADA	Class-I	Class-II	Class-III	Class-IV
AUSTRALIA	Class-I	Class-II-a, II-b	Class-III	-

International Organization for Standardization (ISO)

A non-governmental organization that develops and publishes international standards on a wide range of subjects, including medical equipment. For the consumer, ISO International Standards ensure that products and services are safe, reliable and of good quality. For businesses, they are strategic tools that reduce costs by minimizing waste and errors and increasing productivity. These standards are very relevant for medical devices and encompass virtually every aspect of the device

Design and implementation – from device inspection requirements to guidelines for medical device labels [2].
It could be about making a product, dealing with a process, conveying a service, or supplying materials – standards cover a wide range of accomplishments.
Standards are the garnered astuteness of people with capability in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, vendors, consumers, patrons, clientele connotation, users, or regulators.
ISO today-ISO has developed over 24222 International Standards and all are included in the ISO Standards catalog
Members-ISO: a global network of national standards bodies. Our members are the foremost standards organizations in their countries and there is only one member per country. Each member represents ISO in its country [3].
Some of the most common reference standards for device manufacturers to follow include:

Sl.No	Standard	Latest Version	Application
1.	ISO 14971	2016	Risk Management of Medical Device.
2.	ISO 9001	2015	Business Quality Management System
3.	ISO 13485	2016	Quality Management System of Medical Device.
4.	ISO 15223	2021	Symbols To Be Used with Medical Devices.
5.	ISO 11135	2014	Ethylene Oxide Sterilization of Medical Devices.
6.	ISO 11607	-	Sterilized Product Packaging for Medical Devices.
7.	ISO 62304	2006	Software Used in Medical Devices.
8.	ISO 109993	-	Biological Evaluation of Medical Devices.
9.	ISO 11137	-	Sterilization Packaging Product of Medical Devices.
10.	ISO 62366-1	2007	Part-1: Application of Usability Engineering to Medical Devices.
11.	ISO 80369-1	-	Small – Bore Connectors for Liquids and Gases in Health Care Applicants.
12.	ISO 14155	2020	Clinical Investigation of Medical Devices for Human Subjects, GCP.
13.	ISO 19001	2013	In Vitro Diagnostic Medical Devices
14.	ISO 16571	-	System For Evacuation of Plume Generated by Medical Devices.
15.	ISO 20417	2021	Medical Devices-Information to Be Supplied by The Manufacturer.
16	ISO 28620	2020	Medical Devices-Non -Electrically Driven Portable Infusion Devices.
17.	ISO 17510	2015	Medical Devices- Sleep Apnoea Breathing healing -Masks and Applications Accessories.
18.	ISO 5137	-	Active Medical Device- Good Engineering Maintenance Management.
19.	ISO 15225	2016	Medical Devices-Quality Management-Medical Device Nomenclature Data Structure.
20.	ISO 15225	2010	Medical Devices-Quality Management-Medical Device Nomenclature Data Structure
21.	ISO 13485	2003	Medical Devices-QMS-Requirements for Regulatory Purposes.
22.	ISO 18779	2005	Medical Devices for Conserving Oxygen and Oxygen Mixtures-Particular Requirements.
23.	ISO 16142-1	2016	Recognized Essential Principles of Safety and Performance of Medical Devices. (Part-1)
24.	ISO 22442-3	2007	Medical Devices Utilizing Animal Tissues and Their Derivatives. (Part-3)
25.	ISO 24971	2020	Medical Devices-Guidance on The Application of Iso 14971.
26.	ISO 22442-2	2020	Medical Device Utilizing Animal Tissues and Derivatives-(Part-2): Controls on Sourcing, Collection & Handling.

27.	ISO 20416	2020	Medical Devices-Post-Market Surveillance for Manufacturers.
28.	ISO 23128	2019	Medical Devices – Transfusion Set and Blood Bag Compatibility Test Method.
29.	ISO 18250-6	2019	Medical Devices – Connectors for Reservoir Delivery Systems for Health Care Applications-Part 6: Neural Applications.
30.	ISO 18250-7	2018	Medical Devices – Connectors for Reservoir Delivery Systems for Health Care Applications-Part 7: Connectors for Intravascular Infusion
31.	ISO 18250-1	2018	Medical Devices – Connectors for Reservoir Delivery Systems for Health Care Applications- Part 1: General Requirements and Common Test Methods.
32.	ISO 18250-8	2018	Medical Devices – Connectors for Reservoir Delivery Systems for Health Care Applications- Part 8: Citrate-Based Anti-Coagulant Solution for Apheresis Applications.
33.	ISO 18250-3	2018	Medical Devices – Connectors for Reservoir Delivery Systems for Health Care Applications – Part 3: Enteral Applications.
34.	ISO 19727	2017	Medical devises Pump Tube Spallation Test – General Procedure.
35.	ISO 16142-2	2017	Recognized Essential Principles of Safety and Performance of Medical Devices. Part-2 Essential Principles for All IVD Medical Devices and Guidance on Selection of Standards.
36.	ISO 18250	-	Cleanliness Of Medical Devices-Process Design and Test Methods.
37.	ISO 13485	1996	Quality Systems-Medical Devices-Particular Requirements for The Application of ISO 9001.
38.	ISO 14969	1999	Quality Systems-Medical Devices-Guidance on The Application of ISO 13485 and ISO 13488.
39.	ISO 6717	2021	IVD Medical Devices-Single-Use Containers for The Collection of Specimens from Humans Other Than Blood.
40.	ISO 17664	2004	Sterilization of Medical Devices-Information Provided by Manufacturers for The Processing of Re-sterilizable Medical Devices.
41.	ISO 20225	2001	Global Medical Device Nomenclature for The Purpose of Regulatory Data Exchange.
42.	ISO 13488	1996	Quality Systems-Medical Devices-Particular Requirements for The Application of ISO 9002.
43.	ISO 14117	2012	Active Implantable Medical Devices-Electromagnetic Compatibility- EMC Test Protocols for Implantable Cardiac Pacemakers, Implantable Cardioverter Defibrillators and Cardiac Resynchronization Devices.
44.	ISO 25424	2009	Sterilization of Medical Devices-Low Temperature Steam and Formaldehyde-Requirements for Development, Validation and Routine Control of a Sterilization process for Medical Devices.
45.	ISO 19218	2011	Medical Devices Hierarchical Coding Structure for Adverse Events-Part 1: Event-Type Codes.

46.	ISO 27186	2010&2020	Active Implantable Devices-Four-Pole Connector System for Implantable Cardiac Rhythm Management Devices-Dimensional and Test Requirements.
47.	ISO 15194	2009	IVD Medical Devices-Measurement of Quantities in Samples of Biological Origin-Requirements for Certified Reference Materials and The Content of Supporting Documentation.
48.	ISO 15193	2002&2009	IVD Medical Devices-Measurement of Quantities in Samples of Biological Origin-Requirements for Content and Presentation of Reference Measurement Procedures.
49.	ISO 19218-2	2012	Medical Devices–Hierarchical Coding Structure for Adverse Events Part 2: Evaluation Codes.
50.	ISO 80002-2	2017	Medical Device Software-Part 2: Validation of Software for Medical Device Quality Systems.
51.	ISO 22442-4	2010	Medical Devices Utilizing Animal Tissues and Their Derivatives-Part 4: Principles for Inactivation of Transmissible Spongiform Encephalopathy Agents and Validation Assays for Those Processes.
52.	ISO 16142	1999	Medical Devices-Guidance on The Selection of Standards in support of Recognized Essential Principles of Safety and Performance of Medical Devices.
53.	ISO 22442-1	2007	Medical Devices Utilizing Animal Tissues and Their Derivatives-Part 1: Application of Risk Management.
54.	ISO 10993-33	2015	Biological Evaluation of Medical Devices-Part 33: Guidance on Tests to Evaluate Genotoxicity- Supplement to ISO 10993-3.
55.	ISO 37137	2014	Cardiovascular Biological Evaluation of Medical Devices-Guidance for Absorbable Implants.
56.	ISO 10993-22	2017	Biological Evaluation of Medical Devices-Part 22: Guidance on Nanomaterials.
57.	ISO 11607-1	2019	Packaging For Terminally Sterilized Medical Devices-Part-1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems.
58.	ISO 11607-2	2019	Packaging For Terminally Sterilized Medical Devices-Part-2: Validation Requirements for Forming, Sealing and Assembly Process.
59.	ISO 7405	2018	Dentistry-Evaluation of Biocompatibility of Medical Devices Used in Dentistry.
60.	ISO 10993-20	2006	Biological Evaluation of Medical Devices-Part-20: Principles and Methods for Immunotoxicology Testing of Medical Devices.
61.	ISO 10993-19	2020	Biological Evaluation of Medical Devices-Part 19: Physio-Chemical, Morphological and Topographical Characterization of Materials.
62.	ISO 10993-5	1992	Biological Evaluation of Medical Devices-Part 5: Tests for Cytotoxicity: In Vitro Methods.
63.	ISO 19993-1	1992	Biological Evaluation of Medical Devices-Part 1: Guidance on Selection of Tests.
64.	ISO 16775	2021	Packaging For Terminally Sterilized Medical Devices- Guidance on The Application of ISO 11607-1 and ISO 1160-2
65.	ISO 21387	2020	Sterilization of Medical Devices-Guidance on The Requirements for The Validation and Routine Processing of Ethylene Oxide Sterilization Process Using Parametric Release.

66.	ISO 17511	2020	IVD Medical Devices-Requirements for Sterilization for Establishing Metrological Traceability of Values Assigned to Calibrators, Trueness Control Materials and Human Samples.
67.	ISO 18153	2003	IVD Medical Devices-Measurement of Quantities in Biological Samples-Metrological Traceability of Values for Catalytic Concentration of Enzymes Assigned Calibrators and Control Materials.
68.	ISO 20916	2019	IVD Medical Devices-Clinical Performance Studies Using Specimens from Human Subjects-Good Study Practice.
69.	ISO 23640	2011	IVD Medical Devices-Evaluation of Stability of IVD Reagents.
70.	ISO 181135-5	-	IVD Medical Devices-Information Supplied by The Manufacturer (Labelling)-Part 5: IVD Instruments for Self-Testing.
71.	ISO 11796	-	Biological Evaluation of Medical Devices-Guidance for Interlaboratory Studies to Demonstrate the Applicability of Validated In-Vitro Methods to Assess the Skin Sensitization of Medical devices.
72.	ISO 10993-6	-	Biological Evaluation of Medical Devices-Part 6: Biological Evaluation of Medical Devices.
73.	ISO 10993-7	2008	Biological Evaluation of Medical Devices part 7: Ethylene Oxide Sterilization Residuals.
74.	ISO 10993-12	2007&2021	Biological Evaluation of Medical Devices-Part 12: Sample separation and Reference Materials.
75.	ISO 21726	2019	Biological Evaluation of Medical Devices-Application of Threshold of Toxicology Concern for Assessing Biocompatibility of Medical Device Constituents.
76.	ISO 10993-4	2002&2017	Biological Evaluation of Medical Devices-Part 4: Selection of Tests for Interactions with Blood.
77.	ISO 15499	2012	Biological Evaluation of Medical Devices-Guidance on the Conduct of Biological Evaluation within A Risk Management Process.
78.	ISO 13485	2003	Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes-Technical Corrigendum.
79.	ISO 10993-11	2006	Biological Evaluation of Medical Devices-Part 11: Tests for Systemic Toxicity.
80.	ISO 18113-1	-	IVD Medical Devices-Information Supplied by The Manufacturer (Labelling)-Part 1: Terms, Definitions, and General Requirements.
81.	ISO 18113-2	-	IVD Medical Devices-Information Supplied by The Manufacturer (Labelling)-Part 2: IVD Reagents for Professional Use.
82.	ISO 18113-3	-	IVD Medical Devices-Information Supplied by The Manufacturer (Labelling)-Part 3: IVD Instruments for Professional Use.
83.	ISO 18113-4	-	IVD Medical Devices-Information Supplied by The Manufacturer (Labelling)-Part 4: IVD Reagents for Self-Testing.
84.	ISO 10993-17	-	Biological Evaluation of Medical Devices-Part 17: Toxicological Risk Assessment of Medical Device Constituents.
85.	ISO 21474-2	-	IVD Medical Devices-Multiplex Molecular Testing for Nucleic Acids-Part 2: Validation and Verification.
86.	ISO 21474-3	-	IVD Medical Devices-Multiplex Molecular Testing for Nucleic Acids-Part 3: Interpretation and Reports.

87.	ISO 11737-1	2006	Sterilization Of Medical Devices-Microbiological Methods-Part 1: Determination of A Population of Microorganisms on Products.
88.	ISO 11737-2	2009	Sterilization of Medical Devices-Microbiological Methods-Part 2: Tests of Sterility Performed in The Definition, Validation and Maintenance of a Sterilization Process.
89.	ISO 11737-3	2004	Sterilization of Medical Devices-Microbiological Methods-Part 3: Guidance on Evaluation and Interpretation of Bioburden Data.
90.	ISO 10993-10	2021	Biological Evaluation of Medical Devices-Part 10: Tests for Skin Sensitization.
91.	ISO 10993-23	2021	Biological Evaluation of Medical Devices-Part 23: Tests for Irritation.
92.	ISO 10993-16	2017	Biological Evaluation of Medical Devices-Part 16: Toxicokinetic Study Design for Degradation of Products and Lech Ables.
93.	ISO 10993-14	2001	Biological Evaluation of Medical Devices-Part 14: Identification and Qualification of Degradation Products from Ceramics.
94.	ISO 10993-2	2006	Biological Evaluation of Medical Devices-Part 2: Animal Welfare Requirements.
95.	ISO 10993-13	2010	Biological Evaluation of Medical Devices-Part 13: Identification and Quantification of Degradation Products from Polymeric Medical Devices.
96.	ISO 10993-18	2020	Biological Evaluation of Medical Devices-Part 18: Chemical Characterization of Medical Device Materials Within a Risk Management Process.
97.	ISO 21474	2020	IVD Medical Devices-Multiplex Molecular Testing for Nucleic Acids-Part 1: Terminology and General Requirements for Nucleic Acid Quality Evaluation.
98.	IS0 11737-2	1998	Sterilization of Medical Devices-Microbiological Methods Part 2: Tests of Sterility Performed in The Validation of a Sterilization Process.
99.	ISO 16142-2	2017	Medical Devices-Recognized Essential Principles of Safety and Performance of Medical Devices. Part-2 Essential Principles and Additional Specific Principles for All IVD Medical Devices and Guidance on Selection of Standards.
100.	ISO 17664-2	2021	Information Provided by Medical Device Manufacturer for Processing of Medical Devices-Part 2: Noncritical Medical Devices.

Conclusion

Medical device standards regulate and maintain products conventionally during the strategy and assembling of medical devices. These standards are utilized both natively and internationally to ensure quality and steadiness between altered products. These standards govern the design and manufacturing of a broad range of products that treat and diagnose various illnesses and injuries. Standards ensure that medical devices have the highest safety and quality that doctors can rely upon to treat medical problems and diseases.

References

1. Medical device definition, accessed on (23 March 2022)- https://www.researchgate.net/publication/326597290_QUALITY_STANDARDS_FOR_MEDICAL_DEVICES.
2. ISO standards accessed on(23-march-2022) available from- https://bioe.uw.edu/wp-content/uploads/2013/07/StandardsHandout_2013.pdf.
3. ISO standards accessed on (23-march-2022) available from-https://www.iso.org/benefits-of-standards.html
4. Medical device standards accessed on (23-Mar-2022) available from-https://www.nqa.com/en-us/certification/sectors/medical-devices-services.
5. ISO standards accessed on (23-march-2022) available from- https://www.rqmplus.com/blog/quick-guide-to-medical-device-standards-iso-standards-and-beyond.
6. Classificationg1.pdf – CDSCO, accessed 23 March 2022, https://cdsco.gov.in .
7. Classify Your Medical Device | FDA, accessed 23 March 2022, https://www.fda.gov
8. MDCG 2021-24 Guidance on classification of medical device, accessed 23 March 2022, https://ec.europa.eu

9. Classification of Medical devices – Canada, accessed 23 March 2022, https://medicaldevices.freyrsolutions.com/medical-devices-regulatory-services-canada
10. Classification of Medical Device- Australia, accessed 23 March 20022, https://www.emergobyul.com/services/australia/tga-device-registration#:~:text=Medical%20device%20classification%20in%20Australia,increases%20with%20increasing%20risk%20level
11. iso standards accessed on (23-march-2022) available from-https://www.greenlight.guru/blog/iso-standards
12. iso standards accessed on (23-march-2022) available from-https://www.iso.org/popular-standards.html.