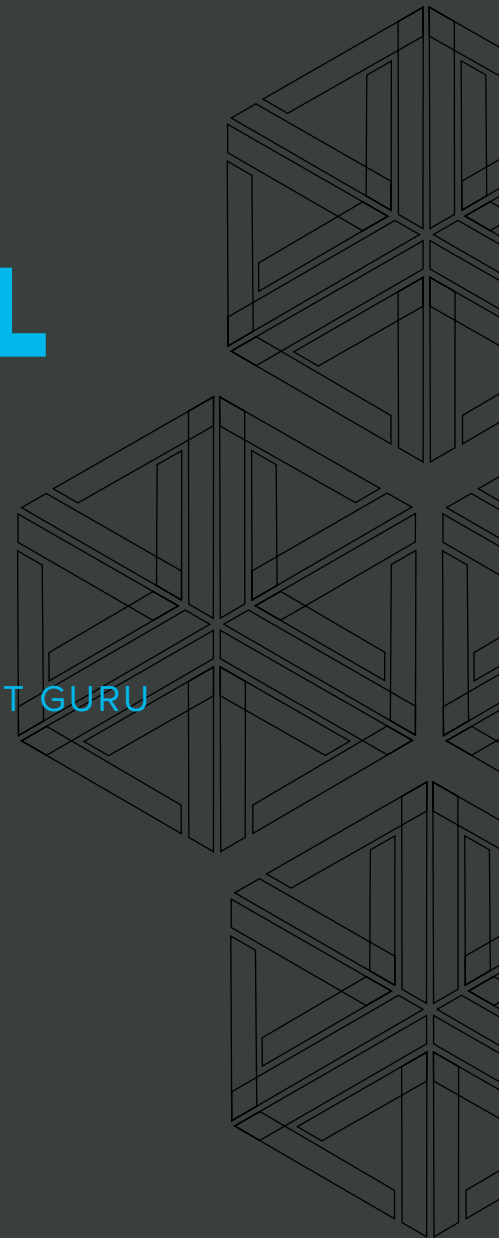EBOOK

ULTIMATE LIST OF ISO STANDARDS FOR MEDICAL DEVICES

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ULTIMATE LIST OF ISO STANDARDS FOR MEDICAL DEVICES

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OVERVIEW

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!

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01 ISO 13485 | MEDICAL DEVICES — QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS FOR REGULATORY PURPOSES

Edition: 3

Publication Year: 2016

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? No

ISO 13485 specifies the requirements for a medical device manufacturer's quality management system (QMS). The standard outlines the QMS requirements necessary to prove that the manufacturer is able to produce safe and effective medical devices that meet user needs and comply with all applicable regulations.

02 ISO 14971 | MEDICAL DEVICES — APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

Edition: 3

Publication Year: 2019

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? Yes

ISO 14971 specifies the process for risk management of medical devices, software as a medical device (SaMD), and in vitro medical devices. The standard outlines a process for medical device manufacturers to identify hazards, evaluate the risks associated with them, and implement risk controls. Risk management as

defined within the standard applies to all stages of the medical device lifecycle and should be an ongoing process.

03 IEC 62304 | MEDICAL DEVICE SOFTWARE — SOFTWARE LIFE CYCLE PROCESSES

Edition: 1

Publication Year: 2015

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? Yes

IEC 62304 specifies a framework for the processes, activities, and tasks that occur throughout the lifecycle of medical device software. This standard defines the lifecycle for Software as a Medical Device (SaMD), software as a component of a medical device, or software that is used in the production of a medical device.

04 IEC 62366-1 | MEDICAL DEVICES — PART 1: APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

Edition: 1

Publication Year: 2015

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? Yes

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ISO 62366-1 specifies the usability engineering process for medical devices, also known as human factors engineering. The standard offers guidance for manufacturers in analyzing, developing, and evaluating the usability of their medical device, as well as how to assess and mitigate any risks associated with the normal use of the device.

Amendment 1: IEC 62366-1:2015/AMD 1:2020

05 | **ISO 11135** | **STERILIZATION OF HEALTH-CARE PRODUCTS — ETHYLENE OXIDE — REQUIREMENTS FOR THE DEVELOPMENT, VALIDATION AND ROUTINE CONTROL OF A STERILIZATION PROCESS FOR MEDICAL DEVICES**

> **Edition:** 2
> **Publication Year:** 2014
> **Technical Committee:** ISO/TC 198 Sterilization of health care products
> **FDA recognized consensus standard?** Yes

ISO 11135 specifies the process for sterilization of a medical device using ethylene oxide. The standard offers guidance on developing, validating, and controlling the process in both industrial and healthcare settings.

Amendment 1: ISO 11135:2014/AMD 1:2018

06 | ISO 15223-1 | MEDICAL DEVICES — SYMBOLS TO BE USED WITH INFORMATION TO BE SUPPLIED BY THE MANUFACTURER — PART 1: GENERAL REQUIREMENTS

Edition: 4

Publication Year: 2021

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? No

ISO 15223-1 specifies the symbols that medical device manufacturers will use to express certain information they supply with a medical device. These symbols can be placed on the packaging of the medical device, its accompanying information, or on the device itself.

07 | ISO 80369-1 | SMALL-BORE CONNECTORS FOR LIQUIDS AND GASES IN HEALTHCARE APPLICATIONS — PART 1: GENERAL REQUIREMENTS

Edition: 2

Publication Year: 2018

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? Yes

ISO 80369-1 specifies manufacturing requirements for small-bore connectors used in fields such as breathing systems, limb cuff inflation, and intravascular or

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hypodermic. The standard provides methods for assessing these connectors, which convey liquids or gasses, and helping reduce the risk of misconnections.

08 ## ISO 11607-1 | PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES — PART 1: REQUIREMENTS FOR MATERIALS, STERILE BARRIER SYSTEMS AND PACKAGING SYSTEMS

Edition: 2

Publication Year: 2019

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? Yes

ISO 11607-1 specifies the methods and requirements for sterile packaging. The standard elucidates the requirements for materials, performed sterile barrier systems, and packaging systems, and is applicable in any situation where medical devices must be sterilized and placed in sterile barrier systems.

09 ## ISO 11607-2 | PACKAGING FOR TERMINALLY STERILIZED MEDICAL DEVICES — PART 2: VALIDATION REQUIREMENTS FOR FORMING, SEALING AND ASSEMBLY PROCESSES

Edition: 2

Publication Year: 2019

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? Yes

ISO 11607-2 specifies the requirements for developing and validating a process for packaging terminally sterilized medical devices. This standard provides guidance on forming, sealing, and assembling a sterile barrier system and packaging system.

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**

Edition: 1

Publication Year: 2006

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? Yes

ISO 11137-1 specifies the requirements for developing, validating, and controlling the radiation sterilization process using the radionuclides Cobalt 60 and Cesium 137, as well as electron and X-ray beams. This standard is limited in scope to medical devices, but it does offer guidance that may be applicable to other products.

Amendment 1: ISO 11137-1:2006/AMD 1:2013

Amendment 2: ISO 11137-1:2006/AMD 2:2018

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11 | ISO 14155 | CLINICAL INVESTIGATION OF MEDICAL DEVICES FOR HUMAN SUBJECTS — GOOD CLINICAL PRACTICE

Edition: 3

Publication Year: 2020

Technical Committee: ISO/TC 194 Biological and clinical evaluation of medical devices

FDA recognized consensus standard? Yes

ISO 14155 specifies good clinical practice for clinical investigations using human subjects. The standard addresses design, conduct, and reporting of studies used to determine the safety and efficacy of medical devices on real patients.

12 | ISO 19001 | IN VITRO DIAGNOSTIC MEDICAL DEVICES — INFORMATION SUPPLIED BY THE MANUFACTURER WITH IN VITRO DIAGNOSTIC REAGENTS FOR STAINING IN BIOLOGY

Edition: 2

Publication Year: 2013

Technical Committee: ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

FDA recognized consensus standard? No

ISO 19001 specifies the requirements regarding the information manufacturers must supply with reagents used for staining in biology. This standard applies to the producers, suppliers, and vendors of the reagents, and its requirements are a prerequisite for attaining reproducible results.

13 ISO/TR 24971 | MEDICAL DEVICES — GUIDANCE ON THE APPLICATION OF ISO 14971

Edition: 2

Publication Year: 2020

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? No

ISO 24971 is the guidance document for ISO 14971:2019. It offers perspective for medical device manufacturers on developing, implementing, and maintaining a risk management system. The standard provides a holistic approach to the identification, assessment, and control of risks within the medical device lifecycle.

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

Edition: 3

Publication Year: 2019

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? Yes

ISO 11737 specifies the criteria for testing the sterilization of medical devices that have been exposed to a method of sterilization that has been reduced relative to what the manufacturer anticipates will be the normal sterilization process. This type of test is used during the sterilization validation process.

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15   ISO 16571 | SYSTEMS FOR EVACUATION OF PLUME GENERATED BY MEDICAL DEVICES

Edition: 1

Publication Year: 2019

Technical Committee: ISO/TC 121/SC 6 Medical gas supply systems

FDA recognized consensus standard? No

ISO 16571 specifies the requirements for equipment used to evacuate any plume generated by a medical device. This standard covers the design, manufacture, installation, maintenance, and testing of the evacuation equipment.

16   ISO 20916 | IN VITRO DIAGNOSTIC MEDICAL DEVICES — CLINICAL PERFORMANCE STUDIES USING SPECIMENS FROM HUMAN SUBJECTS — GOOD STUDY PRACTICE

Edition: 1

Publication Year: 2019

Technical Committee: ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

FDA recognized consensus standard? No

ISO 20916 defines good study practices for clinical performance studies of in vitro diagnostic (IVD) medical devices. The standard covers planning, designing, conducting, recording, and reporting of clinical studies, and specifies general requirements for reliable, safe, and ethical studies.

17 | IEC 80001-1 | SAFETY, EFFECTIVENESS AND SECURITY IN THE IMPLEMENTATION AND USE FO CONNECTED MEDICAL DEVICES OR CONNECTED HEALTH SOFTWARE — PART 1: APPLICATION OF RISK MANAGEMENT

Edition: 2

Publication Year: 2021

Technical Committee: ISO/TC 215 Health informatics

FDA recognized consensus standard? No

IEC 80001-1 specifies the requirements for applying risk management when connecting a health IT system within a health IT infrastructure. The standard addresses what must be done before, during, and after the connection to ensure safe, effective, and secure use.

18 | IEC/TR 80002-1 | MEDICAL DEVICE SOFTWARE — PART 1: GUIDANCE ON THE APPLICATION OF ISO 14971 TO MEDICAL DEVICE SOFTWARE

Edition: 1

Publication Year: 2009

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? Yes

IEC/TR 80002-1 offers guidance on applying the requirements of ISO 14971 to medical device software. The technical report is intended for risk management professionals and software engineers who need to understand how to comply with the requirements outlined in ISO 14971. While the technical report is focused

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heavily on medical devices, it is also applicable for anyone implementing risk management for software in a healthcare environment.

19 **IEC/TR 80002-2 | MEDICAL DEVICE SOFTWARE — PART 2: VALIDATION OF SOFTWARE FOR MEDICAL DEVICE QUALITY SYSTEMS**

> **Edition:** 1
>
> **Publication Year:** 2017
>
> **Technical Committee:** ISO/TC 210 Quality management and corresponding general aspects for medical devices
>
> **FDA recognized consensus standard?** No

IEC/TR 80002-2 may be applied to software used in any aspect of a medical device quality management system (QMS). The technical report covers design, testing, manufacturing, labelling, packaging, complaint handling, and any other part of a QMS as laid out in ISO 13485. It does not apply to software as part of a medical device or software as a medical device (SaMD).

20 **IEC/TR 80002-3 | MEDICAL DEVICE SOFTWARE — PART 3: PROCESS REFERENCE MODEL OF MEDICAL DEVICE SOFTWARE LIFE CYCLE PROCESSES (IEC 62304)**

> **Edition:** 1
>
> **Publication Year:** 2014
>
> **Technical Committee:** ISO/TC 210 Quality management and corresponding general aspects for medical devices
>
> **FDA recognized consensus standard?** No

IEC/TR 80002-3 offers a description of the software lifecycle processes for medical devices, derived from IEC 62304. These processes have been aligned with ISO/IEC 12207 and are compliant with ISO/IEC 24774. Together, these three standards form the basis of this technical report.

ISO 10993 — BIOLOGICAL EVALUATION OF MEDICAL DEVICES

The ISO 10993 family comprises more than 20 different standards, all of which describe some part of the biological evaluation of medical devices. Below, we have chosen some of the most searched for standards within the family for further explanation; however, you can find the full list of ISO 10993 standards here.

21 **ISO 10993-1 | BIOLOGICAL EVALUATION OF MEDICAL DEVICES — PART 1: EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS**

Edition: 5

Publication Year: 2018

Technical Committee: ISO/TC 194 Biological and clinical evaluation of medical devices

FDA recognized consensus standard? Yes

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ISO 10993-1 specifies the principles of biological evaluation of medical devices within a risk management framework, as well as how to categorize devices based on the type and duration of contact they have with the human body. The standard applies to devices that will have direct or indirect contact with a patient or user's body during its intended use.

22 **ISO 10993-2 | BIOLOGICAL EVALUATION OF MEDICAL DEVICES — PART 2: ANIMAL WELFARE REQUIREMENTS**

Edition: 2

Publication Year: 2006

Technical Committee: ISO/TC 194 Biological and clinical evaluation of medical devices

FDA recognized consensus standard? Yes

ISO 10993-2 covers the welfare of animals that are tested on to assess the biocompatibility of any materials used in medical devices. It specifies the requirements necessary to prove that animal welfare has been accounted for by those commissioning and designing animal tests. It also provides guidance on reducing the number of animals used and reducing or eliminating any pain or distress in the animals being tested upon.

23 ISO 10993-4 | BIOLOGICAL EVALUATION OF MEDICAL DEVICES — PART 4: SELECTION OF TESTS FOR INTERACTIONS WITH BLOOD

Edition: 3

Publication Year: 2017

Technical Committee: ISO/TC 194 Biological and clinical evaluation of medical devices

FDA recognized consensus standard? Yes

ISO 10993-4 specifies the requirements for evaluating the interaction of medical devices with blood. The standard provides guidance on the classification of medical devices, the evaluation of a device's interaction with blood, and the rationale for selecting tests.

24 ISO 10993-5 | BIOLOGICAL EVALUATION OF MEDICAL DEVICES — PART 5: TESTS FOR IN VITRO CYTOTOXICITY

Edition: 3

Publication Year: 2009

Technical Committee: IISO/TC 194 Biological and clinical evaluation of medical devices

FDA recognized consensus standard? Yes

ISO 10993-5 offers guidance on methods for testing the in vitro cytotoxicity of medical devices. The methods described use cultured mammalian cells in vitro to determine the appropriate biological parameters.

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25 **ISO 27186** | **ACTIVE IMPLANTABLE MEDICAL DEVICES — FOUR-POLE CONNECTOR SYSTEM FOR IMPLANTABLE CARDIAC RHYTHM MANAGEMENT DEVICES — DIMENSIONAL AND TEST REQUIREMENTS**

Edition: 2

Publication Year: 2020

Technical Committee: ISO/TC 150/SC 6 Active implants

FDA recognized consensus standard? Yes

ISO 27186 specifies a four-pole connector system for implantable cardiac rhythm devices. This standard covers the requirements for the connector portion of an implantable lead and the mating connector cavity. It also provides dimensions and performance requirements for the connector system.

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**

Edition: 2

Publication Year: 2009

Technical Committee: ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

FDA recognized consensus standard? No

ISO 15194 specifies the requirements for certified reference materials and their

supporting documentation. It applies to materials classified as primary measurements standards, secondary measurement standards, and international conventional calibrators.

ISO 15583 — WASHER-DISINFECTORS

The ISO 15583 family of standards includes seven different standards, which cover the requirements for washer-disinfectors and their accessories. We have included some of the most searched for standards below; however, you can find the entire list of ISO 15583 standards here.

27 ISO 15883-1 | WASHER DISINFECTORS — PART 1: GENERAL REQUIREMENTS, TERMS AND DEFINITIONS AND TESTS

Edition: 1

Publication Year: 2006

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? No

ISO 15883-1 specifies the performance requirements for washer-disinfectors and accessories used for cleaning and disinfecting reusable medical devices and other materials. This standard also provides methods for validation, routine control, and periodic monitoring.

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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.

Edition: 1

Publication Year: 2006

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? No

ISO 15883-2 specifies requirements for washer-disinfectors that are used for thermal disinfection of reusable medical devices such as surgical instruments, bowls, dishes, and utensils. These requirements are applied in addition to the general requirements of ISO 15883-1.

29 — ISO 15883-5 | WASHER DISINFECTORS — PART 5: PERFORMANCE REQUIREMENTS AND TEST METHOD CRITERIA FOR DEMONSTRATING CLEANING EFFICACY

Edition: 1

Publication Year: 2021

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? No

ISO 15883-5 specifies the tests and procedures that manufacturers can use to

demonstrate the effectiveness of washer-disinfectors that are used to clean reusable medical devices.

30 **ISO 9626** | STAINLESS STEEL NEEDLE TUBING FOR THE MANUFACTURE OF MEDICAL DEVICES — REQUIREMENTS AND TEST METHODS

> **Edition:** 2
>
> **Publication Year:** 2016
>
> **Technical Committee:** ISO/TC 84 Devices for administration of medicinal products and catheters
>
> **FDA recognized consensus standard?** Yes

ISO 9626 specifies the requirements and test methods for rigid stainless steel needle tubing—the type used for manufacturing hypodermic needles among other medical devices. The standard also specifies the dimensions and mechanical properties of the steel needle tubing.

31 **ISO 11117** | GAS CYLINDERS — VALVE PROTECTION CAPS AND GUARDS — DESIGN, CONSTRUCTION AND TESTS

> **Edition:** 3
>
> **Publication Year:** 2019
>
> **Technical Committee:** ISO/TC 58/SC 2 Cylinder fittings
>
> **FDA recognized consensus standard?** No

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ISO 11117 specifies requirements for valve guards and caps used to protect cylinders of liquified, dissolved, or compressed gases. This standard applies to guards and caps which provide the primary protection for cylinders, but it can also be used to test equipment that is attached to cylinder packages.

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**

Edition: 1

Publication Year: 2016

Technical Committee: ISO/TC 210 Quality Management and corresponding general aspects for medical devices

FDA recognized consensus standard? No

ISO 16142-1 calls out a variety of standards and guides that manufacturers can use to assess the conformity and safety of their medical device. This standard specifies the six general principles of safety and performance that all medical devices—including IVDs—must meet. However, this part of the standard also describes additional principles of safety and performance which are relevant to medical devices that are not IVDs.

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

> **Edition:** 1
>
> **Publication Year:** 2017
>
> **Technical Committee:** ISO/TC 210 Quality management and corresponding general aspects for medical devices
>
> **FDA recognized consensus standard?** No

ISO 16142-2 calls out a variety of standards and guides that manufacturers can use to assess the conformity and safety of their medical device. This standard specifies the six general principles of safety and performance that all medical devices—including IVDs—must meet. However, this part of the standard also covers additional principles of safety that are relevant to IVDs.

34 **ISO 17664-1** | PROCESSING OF HEALTH CARE PRODUCTS — INFORMATION TO BE PROVIDED BY THE MEDICAL DEVICE MANUFACTURER FOR THE PROCESSING OF MEDICAL DEVICES — PART 1: CRITICAL AND SEMI-CRITICAL MEDICAL DEVICES

> **Edition:** 1
>
> **Publication Year:** 2021
>
> **Technical Committee:** ISO/TC 198 Sterilization of health care products
>
> **FDA recognized consensus standard?** No

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ISO 17664-1 specifies the requirements for information provided by medical devices manufacturers for the processing of critical or semicritical medical devices or medical devices that will be sterilized. This standard does not define processing instructions. Instead, it specifies the requirements that will help manufacturers to provide detailed processing instructions.

35 | ISO 17664-2 | PROCESSING OF HEALTH CARE PRODUCTS — INFORMATION TO BE PROVIDED BY THE MEDICAL DEVICE MANUFACTURER FOR THE PROCESSING OF MEDICAL DEVICES — PART 2: NON-CRITICAL MEDICAL DEVICES

Edition: 1

Publication Year: 2021

Technical Committee: ISO/TC 198 Sterilization of health care products

FDA recognized consensus standard? No

ISO 17664-2 specifies the requirements for information provided by medical device manufacturers for the processing of non-critical medical devices that will not be sterilized. This standard does not define processing instructions. Instead, it specifies the requirements that will help manufacturers to provide detailed processing instructions.

36 **ISO 12052** | HEALTH INFORMATICS — DIGITAL IMAGING AND COMMUNICATION IN MEDICINE (DICOM) INCLUDING WORKFLOW AND DATA MANAGEMENT

Edition: 2

Publication Year: 2017

Technical Committee: ISO/TC 215 Health informatics

FDA recognized consensus standard? No

ISO 12052 covers the exchange of digital images between medical imaging equipment and the systems that manage the communication of that information. It also covers the exchange of information related to the production and management of the images.

37 **ISO 14117** | ACTIVE IMPLANTABLE MEDICAL DEVICES — ELECTROMAGNETIC COMPATIBILITY — EMC TEST PROTOCOLS FOR IMPLANTABLE CARDIAC PACEMAKERS, IMPLANTABLE CARDIOVERTER DEFIBRILLATORS AND CARDIAC RESYNCHRONIZATION DEVICES

Edition: 2

Publication Year: 2019

Technical Committee: ISO/TC 150/SC 6 Active implants

FDA recognized consensus standard? Yes

ISO 14117 specifies the testing methods for evaluating the electromagnetic compatibility of certain active implantable cardiovasucalrdevices. It also defines the performance limits of these devices.

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38 ISO 19223 | LUNG VENTILATORS AND RELATED EQUIPMENT — VOCABULARY AND SEMANTICS

Edition: 1

Publication Year: 2019

Technical Committee: ISO/TC 121/SC 4 Vocabulary and semantics

FDA recognized consensus standard? Yes

ISO 19223 specifies the vocabulary for all fields of respiratory care using mechanical ventilation. The terms and semantics it establishes are also applicable to accessories the manufacturer intends to connect to a ventilator when those accessories can affect basic safety or essential performance.

39 ISO/IEEE 11073-10101 | HEALTH INFORMATICS — DEVICE INTEROPERABILITY — PART 10101: POINT-OF-CARE MEDICAL DEVICE COMMUNICATION — NOMENCLATURE

Edition: 2

Publication Year: 2020

Technical Committee: ISO/TC 215 Health informatics

FDA recognized consensus standard? Yes

ISO/IEEE 11073-10101 specifies the nomenclature for the information communicated between point-of-care medical devices and external computer systems. This standard places an emphasis on acute care medical devices and vital signs information, but it also supports an object-oriented information model for medical device communication.

40 ISO 13482 | ROBOTS AND ROBOTIC DEVICES — SAFETY REQUIREMENTS FOR PERSONAL CARE ROBOTS

Edition: 1

Publication Year: 2014

Technical Committee: ISO/TC 299 Robotics

FDA recognized consensus standard? No

ISO 13482 specifies the requirements for designing safe and effective personal care robots. The standard covers the design, protective measures, and information used in mobile servant robots, physical assistant robots, and personal carrier robots. ISO 13482 describes hazards associated with these robots and offers guidelines and requirements for reducing or eliminating risks associated with their use.

41 ISO 18113-1 | IN VITRO DIAGNOSTIC MEDICAL DEVICES — INFORMATION SUPPLIED BY THE MANUFACTURER (LABELLING) — PART 1: TERMS, DEFINITIONS AND GENERAL REQUIREMENTS

Edition: 1

Publication Year: 2009

Technical Committee: ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems

FDA recognized consensus standard? No

ISO 18113-1 specifies the general principles and requirements for information that must be provided by manufacturers along with IVD medical devices. However, it does not cover language requirements, as those fall under the purview of national regulations and legislation.

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42   **ISO 22610 | SURGICAL DRAPES, GOWNS AND CLEAN AIR SUITS, USED AS MEDICAL DEVICES, FOR PATIENTS, CLINICAL STAFF AND EQUIPMENT — TEST METHOD TO DETERMINE THE RESISTANCE TO WET BACTERIAL PENETRATION**

> **Edition:** 2
>
> **Publication Year:** 2018
>
> **Technical Committee:** ISO/TC 94/SC 13 Protective clothing
>
> **FDA recognized consensus standard?** No

ISO 22610 specifies a method for testing the resistance of surgical drapes, gowns, and clean air suits to penetration by bacteria that are carried by a liquid.

43   **ISO 23640 | IN VITRO DIAGNOSTIC MEDICAL DEVICES — EVALUATION OF STABILITY OF IN VITRO DIAGNOSTIC REAGENTS**

> **Edition:** 1
>
> **Publication Year:** 2011
>
> **Technical Committee:** ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems
>
> **FDA recognized consensus standard?** No

ISO 23640 specifies the requirements for evaluating the stability of reagents used with IVDs. This standard can be used when manufacturers are attempting to generate data regarding the establishment of IVD reagent shelf life, IVD reagent stability after first opening, and the monitoring of IVD reagents already on the market.

44 ISO 23747 | ANAESTHETIC AND RESPIRATORY EQUIPMENT — PEAK EXPIRATORY FLOW METERS FOR THE ASSESSMENT OF PULMONARY FUNCTION IN SPONTANEOUSLY BREATHING HUMANS

Edition: 2

Publication Year: 2015

Technical Committee: ISO/TC 121/SC 3 Respiratory devices and related equipment used for patient care

FDA recognized consensus standard? No

ISO 23747 specifies the requirements for peak expiratory flow meters used in the assessment of pulmonary function. This standard includes all medical devices that measure the peak expiratory flow rate in spontaneously breathing patients, whether they are stand-alone devices or part of a larger integrated lung function device.

45 ISO 28620 | MEDICAL DEVICES — NON-ELECTRICALLY DRIVEN PORTABLE INFUSION DEVICES

Edition: 2

Publication Year: 2020

Technical Committee: ISO/TC 76 Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

FDA recognized consensus standard? No

ISO 28620 specifies the requirements and test methods for non-electrically driven portable infusion devices, and can be applied to devices that offer continuous flow and/or bolus neuraxial and intravascular or hypodermic use. This standard covers devices that can be used in either healthcare or non-healthcare settings—either by a patient or healthcare professionals.

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ISO 14708 | IMPLANTS FOR SURGERY — ACTIVE IMPLANTABLE MEDICAL DEVICES

The ISO 14708 family of standards includes seven different standards, which cover the requirements for different types of active implantable medical devices. We have included some of the most searched for standards below; however, you can find the entire list of ISO 14708 standards here.

46 ## ISO 14708-1 | IMPLANTS FOR SURGERY — ACTIVE IMPLANTABLE MEDICAL DEVICES — PART 1: GENERAL REQUIREMENTS FOR SAFETY, MARKING AND FOR INFORMATION TO BE PROVIDED BY THE MANUFACTURER

Edition: 2

Publication Year: 2014

Technical Committee: ISO/TC 150/SC 6 Active implants

FDA recognized consensus standard? Yes

ISO 14708-1 specifies the generally applicable requirements for active implantable medical devices. The standard provides a series of test types that can be carried out on device samples to demonstrate compliance. This standard applies to both electrically powered devices and those that are powered by other means.

47 | ISO 14708-2 | MEDICAL DEVICES — IMPLANTS FOR SURGERY — ACTIVE IMPLANTABLE MEDICAL DEVICES — PART 2: CARDIAC PACEMAKERS

Edition: 2

Publication Year: 2019

Technical Committee: ISO/TC 150/SC 6 Active implants

FDA recognized consensus standard? No

ISO 14708-2 specifies the requirements for active implantable medical devices that treat bradyarrhythmias and cardiac resynchronization. This standard provides a series of test types that can be carried out on device samples to demonstrate compliance. This standard applies to single devices, a combination of devices, or combinations of devices and accessories—even if some of these parts are not implantable.

48 | ISO 14708-5 | IMPLANTS FOR SURGERY — ACTIVE IMPLANTABLE MEDICAL DEVICES — PART 5: CIRCULATORY SUPPORT DEVICES

Edition: 2

Publication Year: 2020

Technical Committee: ISO/TC 150/SC 6 Active implants

FDA recognized consensus standard? Yes

ISO 14708-5 specifies the safety and performance requirements for active implantable circulatory support devices. This standard applies to single devices, a combination of devices, or combinations of devices and accessories—even if some of these parts are not implantable.

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(49) ISO 20417 | MEDICAL DEVICES — INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

Edition: 1

Publication Year: 2021

Technical Committee: ISO/TC 210 Quality management and corresponding general aspects for medical devices

FDA recognized consensus standard? No

ISO 20417 specifies the requirements for information supplied by the manufacturer of a medical device or accessory. The standard also includes the requirements for identification and labels on medical devices, accessories, packaging, marking, and accompanying information.

(50) ISO 22442-1 | MEDICAL DEVICES UTILIZING ANIMAL TISSUES AND THEIR DERIVATIVES — PART 1: APPLICATION OF RISK MANAGEMENT

Edition: 3

Publication Year: 2020

Technical Committee: ISO/TC 194Biological and clinical evaluation of medical devices

FDA recognized consensus standard? Yes

ISO 22442-1 specifies a process for identifying hazards and hazardous situations associated with medical devices using materials of animal origin. This standard should be used in conjunction with ISO 14971, and it offers a procedure for

estimating and evaluating the risks of the hazards and hazardous situations, controlling those risks, and monitoring the effectiveness of those controls.

We created this list for medical device companies because we know how critical ISO standards are to building high-quality medical devices that make it to market—and stay there.

That's why Greenlight Guru's Medical Device Success Platform is aligned with the latest ISO best practices specific to medical device companies. Our goal is to help you navigate the regulatory landscape with ease, and leave you as much time as possible to focus on true quality.

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