INTERNATIONAL STANDARD

ISO 16142-1

First edition
2016-03-01

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

Dispositifs médicaux — Lignes directrices pour le choix des normes correspondant aux principes essentiels reconnus de sécurité et de performance des dispositifs médicaux

Reference number
ISO 16142-1:2016(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This first edition of ISO 16142-1 cancels and replaces ISO/TR 16142:2006, which has been technically revised with the following most significant changes:

— the technical report was converted to a standard to improve the usefulness of the document to authorities having jurisdiction;

— the standard has been developed in two parts, one for non-IVD (*in vitro* diagnostic) medical devices and one for IVD medical devices;

— the essential principles were harmonized with the most recent Global Harmonization Task Force recommendation[5], as well as other major jurisdictions (e.g. U.S. FDA regulation the relevant aspects of the draft European Medical Device Regulation[6]);

— a much more thorough mapping of published reference standards to the essential principles has been included;

— this part of ISO 16142 also includes a more comprehensive description of the use of standards as a tool to demonstrate that a medical device is clinically effective and performs in a safe manner where the medical benefits of the use of the medical device outweigh the risk of the use to the patient;

— this part of ISO 16142 also includes an informative annex as a template for writers of medical device related standards where the content of their standard is mapped to the essential principles.

ISO 16142 consists of the following parts, under the general title *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*

The following parts are under preparation:

— *Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards*

Introduction

Standards and standardization processes can be made more effective by developing a better understanding of the needs and requirements of those who use or who are affected by standards. Improvements in standards will contribute to global harmonization efforts at all levels.

Continuous innovation is the key to the advancement of medical device technology, contributing to more effective healthcare. Ideally, standards supporting or referenced in regulatory requirements are developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness.

The timely development of medical device standards and their periodic revision make medical device standards effective and efficient tools for supporting regulatory systems and for achieving globally compatible regulation.

Voluntary standards and guides can assist manufacturers to comply with legal requirements. If the standards are accepted within a given regulatory system, compliance with such standards can be deemed to satisfy the legal requirements. The regulatory acceptance does not, of itself, imply that such standards are mandatory.

Medical device standards represent a consensus on requirements that foster innovation while protecting public health.

Harmonized compliance with the regulations, a key element of timely market introduction of advance technology, can be facilitated by the appropriate use of relevant medical device standards. This is based on the premise that

— standards are based on experience or, in other words, are retrospective,

— innovation can present unanticipated challenges to experience,

— rigid, mandatory, application of standards can deter innovation,

— operation of a quality management system, subject to assessment, has become widely acknowledged as a fundamental and effective tool for the protection of public health,

— quality management systems include provisions that address both innovation and experience, and

— such provisions of quality management systems include field experience, risk analysis and management, phased reviews, documentation and record keeping, as well as the use of product and process standards.

The essential principles of safety and performance of medical devices, originally developed by the Global Harmonization Task Force (GHTF), revised in 2012 to harmonize regulatory requirements for medical devices worldwide, and now archived by the International Medical Device Regulators Forum (IMDRF). Thus, an update of the original ISO/TR 16142, based on those essential principles, was needed to keep the document in line with the updated essential principles.

In discussing the revision of ISO/TR 16142:2006, ISO/TC 210 decided that the information included was, at the time of writing, in a state of consensus between the stakeholders and had matured enough to elevate the document from a Technical Report (TR) to an International Standard.

In this part of ISO 16142, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— terms defined in Clause 3: bold.

In this part of ISO 16142, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

For the purposes of this part of ISO 16142, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this part of ISO 16142,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this part of ISO 16142, and

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than three years from the date of publication for equipment newly designed and not earlier than five years from the date of publication for equipment already in production.

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

1 Scope

This part of ISO 16142, which includes the essential principles of safety and performance, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to the recognized essential principles that when met, indicate a medical device is safe and performs as intended. This part of ISO 16142 identifies and describes the six general essential principles of safety and performance that apply to all medical devices, including IVD medical devices (*in vitro* diagnostic).

This part of ISO 16142 also identifies and describes the additional essential principles of safety and performance which need to be considered during the design and manufacturing process, which are relevant to medical devices other than IVD medical devices. Future ISO 16142-2 is intended to identify and describe the essential principles of safety and performance, which need to be considered during the design and manufacturing process of IVD medical devices.

NOTE During the design process, the manufacturer selects which of the listed design and manufacturing principles apply to the particular medical device and documents the reasons for excluding others.

This part of ISO 16142 is intended for use as guidance by medical device manufacturers, standards development organizations, authorities having jurisdiction, and conformity assessment bodies.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1135 (all parts), *Transfusion equipment for medical use*

ISO 3107, *Dentistry — Zinc oxide/eugenol cements and zinc oxide/non-eugenol cements*

ISO 3826 (all parts), *Plastics collapsible containers for human blood and blood components*

ISO 5356 (all parts), *Anaesthetic and respiratory equipment — Conical connectors*

ISO 5359, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 5360, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5361:—[1)], *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anaesthetic reservoir bags*

ISO 5364, *Anaesthetic and respiratory equipment — Oropharyngeal airways*

1) To be published.

ISO 5366 (all parts), *Anaesthetic and respiratory equipment — Tracheostomy tubes*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 5832 (all parts), *Implants for surgery — Metallic materials*

ISO 5834 (all parts), *Implants for surgery — Ultra-high-molecular-weight polyethylene*

ISO 5838 (all parts), *Implants for surgery — Metallic skeletal pins and wires*

ISO 5840 (all parts), *Cardiovascular implants — Cardiac valve prostheses*

ISO 5841 (all parts), *Implants for surgery — Cardiac pacemakers*

ISO 6474-1, *Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 7153-1, *Surgical instruments — Metallic materials — Part 1: Stainless steel*

ISO 7197, *Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components*

ISO 7198, *Cardiovascular implants — Tubular vascular prostheses*

ISO 7199, *Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)*

ISO 7206 (all parts), *Implants for surgery — Partial and total hip joint prostheses*

ISO 7207 (all parts), *Implants for surgery — Components for partial and total knee joint prostheses*

ISO 7376, *Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation*

ISO 7396 (all parts), *Medical gas pipeline systems*

ISO 7405, *Dentistry — Evaluation of biocompatibility of medical devices used in dentistry*

ISO 7494 (all parts), *Dentistry — Dental units*

ISO 7864, *Sterile hypodermic needles for single use*

ISO 7886 (all parts), *Sterile hypodermic syringes for single use*

ISO 8185, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

ISO 8536 (all parts), *Infusion equipment for medical use*

ISO 8537, *Sterile single-use syringes, with or without needle, for insulin*

ISO 8637, *Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

ISO 8638, *Cardiovascular implants and extracorporeal systems — Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*

ISO 8827, *Implants for surgery — Staples with parallel legs for orthopaedic use — General requirements*

ISO 8828, *Implants for surgery — Guidance on care and handling of orthopaedic implants*

ISO 8835-7, *Inhalational anaesthesia systems — Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases*

ISO 9168, *Dentistry — Hose connectors for air driven dental handpieces*

ISO 9170 (all parts), *Terminal units for medical gas pipeline systems*

ISO 9360 (all parts), *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gas in humans*

ISO 9583, *Implants for surgery — Non-destructive testing — Liquid penetrant inspection of metallic surgical implants*

ISO 9584, *Implants for surgery — Non-destructive testing — Radiographic examination of cast metallic surgical implants*

ISO 9626, *Stainless steel needle tubing for the manufacturer of medical devices*

ISO 9713, *Neurosurgical implants — Self-closing intracranial aneurysm clips*

ISO 10079 (all parts), *Medical suction equipment*

ISO 10524 (all parts), *Pressure regulators for use with medical gases*

ISO 10555 (all parts), *Intravascular catheters — Sterile and single-use catheters*

ISO 10651 (all parts), *Lung ventilators for medical use — Particular requirements for basic safety and essential performance*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11040 (all parts), *Prefilled syringes*

ISO/IEEE 11073 (all parts), *Health informatics — Personal health device communication*

ISO 11135 (all parts), *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*

ISO 11138 (all parts), *Sterilization of health care products — Biological indicators*

ISO 11140 (all parts), *Sterilization of health care products — Chemical indicators*

ISO 11197, *Medical supply units*

ISO 11318, *Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements*

ISO 11607 (all parts), *Packaging for terminally sterilized medical devices*

ISO 11608 (all parts), *Needle-based injection systems for medical use — Requirements and test methods*

ISO 11663, *Quality of dialysis fluid for haemodialysis and related therapies*

ISO 11737 (all parts), *Sterilization of medical devices — Microbiological methods*

ISO/TS 13004, *Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD*

ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

ISO 13408 (all parts), *Aseptic processing of health care products*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13779 (all parts), *Implants for surgery — Hydroxyapatite*

ISO 13782, *Implants for surgery — Metallic materials — Unalloyed tantalum for surgical implant applications*

ISO 13958, *Concentrates for haemodialysis and related therapies*

ISO 13959, *Water for haemodialysis and related therapies*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

ISO 14161, *Sterilization of health care products — Biological indicators — Guidance for the selection, use and interpretation of results*

ISO 14242 (all parts), *Implants for surgery — Wear of total hip-joint prostheses*

ISO 14243 (all parts), *Implants for surgery — Wear of total knee-joint prostheses*

ISO 14408, *Tracheal tubes designed for laser surgery — Requirements for marking and accompanying information*

ISO 14457, *Dentistry — Handpieces and motors*

ISO 14602, *Non-active surgical implants — Implants for osteosynthesis — Particular requirements*

ISO 14607, *Non-active surgical implants — Mammary implants — Particular requirements*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14644, *Cleanrooms and associated controlled environments*

ISO 14698, *Cleanrooms and associated controlled environments — Biocontamination control*

ISO 14708 (all parts), *Implants for surgery — Active implantable medical devices*

ISO 14879, *Implants for surgery — Total knee-joint prostheses*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO/TR 14969, *Medical devices — Quality management systems — Guidance on the application of ISO 13485: 2003*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 15002, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15882, *Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results*

ISO 15883 (all parts), *Washer-disinfectors*

ISO 15985, *Plastics — Determination of the ultimate anaerobic biodegradation under high-solids anaerobic-digestion conditions — Method by analysis of released biogas*

ISO 16061, *Instrumentation for use in association with non-active surgical implants — General requirements*

ISO 17510, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

ISO 18777, *Transportable liquid oxygen systems for medical use — Particular requirements*

ISO 18778, *Respiratory equipment — Infant monitors — Particular requirements*

ISO 19054, *Rail systems for supporting medical equipment*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 21534, *Non-active surgical implants — Joint replacement implants — Particular requirements*

ISO 21535, *Non-active surgical implants — Joint replacement implants — Specific requirements for hip-joint replacement implants*

ISO 21536, *Non-active surgical implants — Joint replacement implants — Specific requirements for knee-joint replacement implants*

ISO 21649, *Needle-free injectors for medical use — Requirements and test methods*

ISO 21969, *High-pressure flexible connections for use with medical gas systems*

ISO 22442 (all parts), *Medical devices utilizing animal tissues and their derivatives*

ISO 22523, *External limb prostheses and external orthoses — Requirements and test methods*

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*

ISO 22612, *Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration*

ISO 22675, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

ISO 23328 (all parts), *Breathing system filters for anaesthetic and respiratory use*

ISO 23500, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies*

ISO 23747, *Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans*

ISO 23907, *Sharps injury protection — Requirements and test methods — Sharps containers*

ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

ISO/TR 24971, *Medical devices — Guidance on the application of ISO 14971*

ISO 25424, *Sterilization of medical devices — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 25539 (all parts), *Cardiovascular implants — Endovascular devices*

ISO 26722, *Water treatment equipment for haemodialysis applications and related therapies*

ISO 27186, *Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements*

ISO 80369 (all parts), *Small-bore connectors for liquids and gases in healthcare applications*

ISO 81060 (all parts), *Non-invasive sphygmomanometers*

ISO/IEC 15026 (all parts), *Systems and software engineering — Systems and software assurance*

IEC/ISO 80601-2, *Medical electrical equipment*

IEC 60118-15, *Electroacoustics — Hearing aids — Part 15: Methods for characterizing single processing in hearing aids with a speech-like signal*

IEC 60336, *Medical electrical equipment — X-ray tube assemblies for medical diagnosis - Characteristics of focal spots*

IEC 60417, *Graphical symbols for use on equipment*

IEC 60522, *Determination of the permanent filtration of X-ray tube assemblies*

IEC 60580, *Medical electrical equipment — Dose area product meters*

IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-3, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-1-9, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-11, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-12, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment*

IEC 60601-2 (all parts), *Medical electrical equipment*

IEC 60627, *Diagnostic X-ray imaging equipment — Characteristics of general purpose and mammographic anti-scatter grids*

IEC 60731, *Medical electrical equipment — Dosimeters with ionization chambers as used in radiotherapy*

IEC 60812, *Analysis techniques for system reliability — Procedure for failure mode and effects analysis (FMEA)*

IEC 60825, *Safety of laser products — Part 1: Equipment classification and requirements*

IEC 60878, *Graphical symbols for electrical equipment in medical practice*

IEC 60976, *Medical electrical equipment — Medical electron accelerators — Functional performance characteristics*

IEC 61168, *Radiotherapy simulators — Functional performance characteristics*

IEC 61217, *Radiotherapy equipment — Coordinates, movements and scales*

IEC 61223-2-6, *Evaluation and routine testing in medical imaging departments — Part 2-6: Consistency tests imaging performance of computed tomography X-ray equipment*

IEC 61223-3, *Evaluation and routine testing in medical imaging departments — Part 3-4: Acceptance tests — Imaging performance of dental X-ray equipment*

IEC 61303, *Medical electrical equipment — Radionuclide calibrators — Particular methods for describing performance*

IEC 61391 (all parts), *Ultrasonics — Pulse-echo scanners*

IEC 61674, *Medical electrical equipment — Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging*

IEC 61676, *Medical electrical equipment — Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology*

IEC 61689, *Ultrasonics — Physiotherapy systems — Field specifications and methods of measurement in the frequency range 0,5 MHz to 5 MHz*

IEC 61846, *Ultrasonics — Pressure pulse lithotripters — Characteristics of fields*

IEC 61847, *Ultrasonics — Surgical systems — Measurement and declaration on the basic output characteristics*

IEC 61910-1, *Medical electrical equipment — Radiation dose documentation — Part 1: Radiation dose structured reports for radiography and radioscopy*

IEC 62083, *Medical electrical equipment — Requirements for the safety of radiotherapy treatment planning systems*

IEC 62220 (all parts), *Medical electrical equipment — Characteristics of digital X-ray imaging devices*

IEC 62266, *Medical electrical equipment — Guidelines for implementation of DICOM in radiotherapy*

IEC 62304, *Medical device software — Software life cycle processes*

IEC 62359, *Ultrasonics — Field characterization — Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 62471, *Photobiological safety of lamps and lamp systems*

IEC 62494-1, *Medical electrical equipment — Exposure index of digital X-ray imaging systems — Part 1: Definitions and requirements for general radiography*

IEC 62563-1, *Medical electrical equipment — Medical image display systems — Part 1: Evaluation methods*

IEC 80000 (all parts), *Quantities and units*

IEC 80001-1, *Application of risk management for IT-networks incorporating medical devices — Part 1: Roles, responsibilities and activities*

IEC/TR 80001-2-1, *Application of risk management for IT-networks incorporating medical devices — Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples*

