BS ISO 16142-1:2016

BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of ISO 16142-1:2016. It supersedes PD ISO/TR 16142:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/210, Quality management and corresponding general aspects for medical devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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INTERNATIONAL STANDARD

ISO 16142-1

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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

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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.

INTERNATIONAL STANDARD **ISO 16142-1:2016(E)**

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*

IEC/TR 80002-1, *Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software*

IEC 80003 (all parts), *Physiological quantities and their units*

IEC/ISO 80601-2 (all parts), *Medical electrical equipment*

AAMI TIR49, *Design of training and instructional materials for medical devices used in non-clinical environments*

AAMI HE75, *Human factors engineering — Design of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

ASTM F2027, *Standard Guide for Characterization and Testing of Raw or Starting Biomaterials for Tissue-Engineered Medical Products*

ASTM F2212, *Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)*

ASTM F2761, *Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE For convenience, the sources of all defined terms used in this part of ISO 16142 are given in Annex E.

3.1
authority having jurisdiction
regulatory authority
governmental agency or office assigned to oversee the regulation of a regulated product within a country, jurisdiction, or assigned territory

3.2
basic standard
standard that includes fundamental concepts or principles and specifies requirements with regard to general aspects applicable to a wide range of products, processes, or services

Note 1 to entry: Basic standards are sometimes referred to as horizontal standards and usually apply to more than one field (sector).

3.3
essential principles
essential principles of safety and performance
fundamental high-level requirements that when complied with ensure a medical device is safe and performs as intended

3.4
group standard
basic standard that specifies safety and performance criteria applicable to several or a family of similar products, processes, or services

Note 1 to entry: Group standards are sometimes referred to as semi-horizontal standards and usually apply to one field (sector).

3.5
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:2014, 3.2]

3.6
hazardous situation
circumstance in which people, property, or the environment are exposed to one or more hazard(s)

[SOURCE: ISO/IEC Guide 51:2014, 3.4, modified]

3.7
informative
providing useful or interesting information

Note 1 to entry: Not required for compliance.

3.8
intended use
use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer

[SOURCE: ISO 14971:2007, 2.5]

3.9
IVD medical device
in vitro diagnostic medical device
medical device intended by the manufacturer for the examination of specimens derived from the human body to provide information for diagnostic, monitoring or compatibility purposes

EXAMPLE Reagents, calibrators, specimen collection and storage devices, control materials and related instruments, apparatus or articles.

Note 1 to entry: Can be used alone or in combination with accessories or other medical devices.

[SOURCE: ISO 14971:2007, 2.6]

3.10
life-cycle
all phases in the life of a medical device, from the initial conception to final decommissioning and disposal

[SOURCE: ISO 14971:2007, 2.7]

3.11
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a medical device, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

Note 1 to entry: Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

Note 2 to entry: For a definition of labelling, see ISO 13485:2003, 3.6.

[SOURCE: ISO 14971:2007, 2.8]

3.12
medical device
instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices, and

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF)[5].

Note 2 to entry: Products, which could be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are

— aids for disabled/handicapped people,

— devices for the treatment/diagnosis of diseases and injuries in animals,

— accessories for medical devices (see Note 3 to entry),

— disinfection substances, and

— devices incorporating animal and human tissues which can meet the requirements of the above definition but are subject to different controls.

Note 3 to entry: Accessories intended specifically by manufacturers to be used together with a parent medical device to enable that medical device to achieve its intended purpose, should be subject to this part of ISO 16142.

[SOURCE: ISO 14971:2007, 2.9, modified]

3.13
normative
providing required information

Note 1 to entry: Required for compliance.

3.14
process standard
standard that specifies requirements for elements of a process used to develop, implement or maintain a stage of the life-cycle of a product or service

Note 1 to entry: A process standard may be a basic standard, group standard or product standard.

3.15
product standard
standard that specifies necessary safety and performance requirements for a specific or a family of product(s), process(es), or service(s) making reference, as far as possible, to basic standards and group standards

Note 1 to entry: Product standards are sometimes referred to as vertical standards.

3.16
post-production
part of the life-cycle of the product after the design has been completed and the medical device has been manufactured

EXAMPLE Transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning and disposal.

[SOURCE: ISO 14971:2007, 2.11]

3.17
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified]

3.18
risk control
process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

[SOURCE: ISO 14971:2007, 2.19]

3.19
risk management
systematic application of management policies, procedures, and practices to the tasks of analysing, evaluating, controlling, and monitoring risk

[SOURCE: ISO 14971:2007, 2.22]

3.20
state of the art
developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience

[SOURCE: ISO/IEC Guide 2:2004, 1.4]

4 Essential principles of safety and performance of medical devices

Medical device standards developers are encouraged to consider the essential principles as design input for the development of new and revised medical device standards. Additional information is found in Annex D.

Medical device performance can include technical functions in addition to clinical effectiveness. Performance is easier to objectively measure and quantify than clinical effectiveness. Performance may be described as how well or accurately a medical device carries out its use(s) as intended by its manufacturer. For some medical devices, medical benefit or clinical effectiveness can only be determined by conducting clinical investigations carried out in human subjects.

The manufacturer of a medical device is expected to design and manufacture a product that is safe and clinically effective throughout its life-cycle. This part of ISO 16142 describes fundamental design and manufacturing criteria, referred to as essential principles of safety and performance, to ensure this outcome. This part of ISO 16142 is structured to provide general essential principles that apply to all medical devices including IVD medical devices. This part of ISO 16142 also includes additional essential principles of safety and performance which are relevant to medical devices other than IVD medical devices that need to be considered during the design and manufacturing process.

Essential principles of safety and performance provide broad, high-level, criteria for design, production, and post-production (including post-market surveillance) throughout the life-cycle of all medical devices, ensuring their safety and performance. The concept of essential principles was developed

by the Global Harmonization Task Force[5]. The concept is intended to encourage convergence in the evolution of regulatory systems for medical devices.

NOTE Some authorities with jurisdiction have more requirements and some have less. Therefore, manufacturers need to understand the requirements of the authorities having jurisdiction in the markets they intend to serve.

Where relevant, to ensure all of the essential principles are met, a manufacturer may use consensus standards that contain detailed requirements demonstrating conformance with the essential principles. Such consensus standards provide a greater level of detail and specificity than can be expressed in the essential principles. Equally, authorities having jurisdiction may find the essential principles and their related standards useful in the fulfilment of pre-market and post-market requirements throughout the life-cycle of medical devices.

Every medical device has a use as intended by its manufacturer. A medical device is clinically effective when it produces the effect or performs the function in a safe manner as intended by its manufacturer relative to

— the medical condition of the patient, or

— the state of the patient where the medical benefits of the use of the medical device outweighs the risk of the use to the patient.

5 Use of standards and guides in support of the essential principles

5.1 Types of standards useful to demonstrate compliance

Basic standards, group standards, product standards, and process standards are the four types of consensus standards. Figure 1 illustrates the relationships between these types of standards. Because basic standards are so broad that they cross multiple sectors as noted in the examples below, it is rare, if ever, that basic standards are used in the medical device sector.

EXAMPLE 1 Management system standard, ISO 9001.

EXAMPLE 2 Environmental management system standard, ISO 14001.

EXAMPLE 3 Risk management standard, ISO 31000.

EXAMPLE 4 Conformity assessment standard, ISO/IEC 17000.

EXAMPLE 5 Protection from electrical shock standard, IEC 61140.

The majority of medical device consensus standards fall within the group standard and product standard types. While process standards are widely used in the medical device sector, they are subtypes of group standards and product standards.

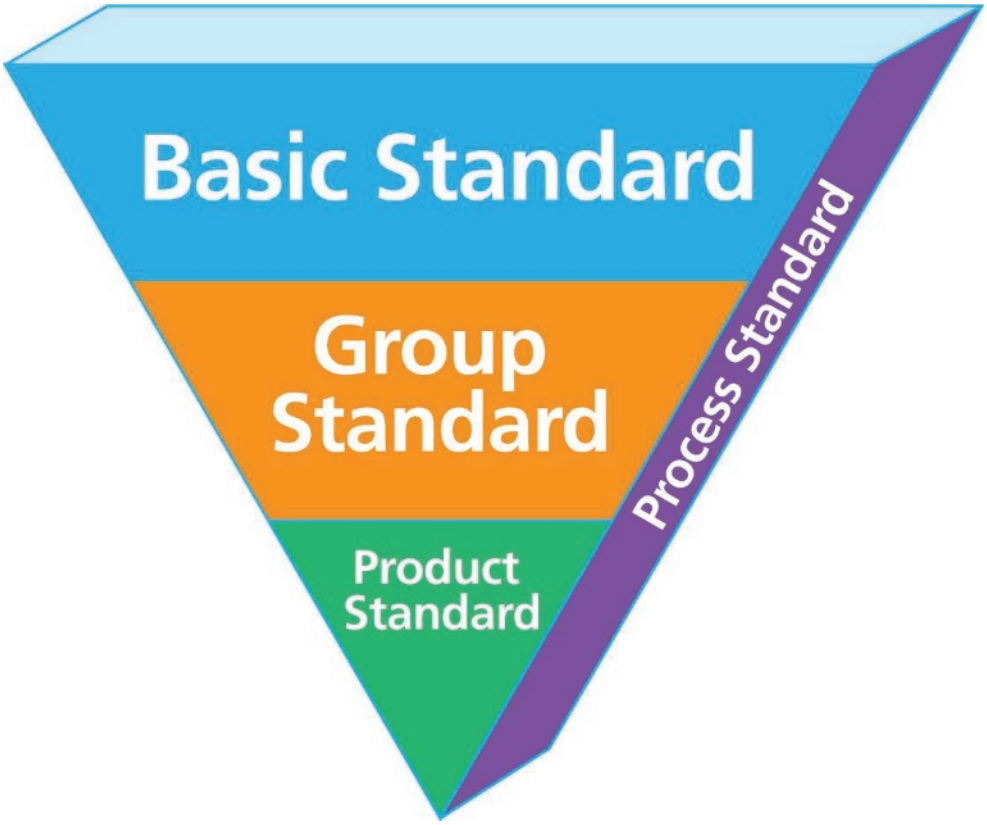

Figure 1 — Types of standards

Group standards are generally horizontal in nature within the medical device sector and are developed to address the essential principles that are applicable to a wide range of medical devices. Examples of group standards include safety standards or standards specifying requirements for a process, such as biological evaluation, general requirements for basic safety and essential performance for medical electrical equipment, sterilization, and usability.

Product standards are typically vertical in nature and provide the technical details needed to satisfy compliance with the essential principles for particular product types. Examples of product standards include standards for defibrillators, hip implants, and respiratory gas monitors. The development and use of international product standards is encouraged as this minimizes the proliferation of regional standards and prevents the development of divergent or conflicting requirements or expectations.

Process standards can be either horizontal or vertical in nature and provide the requirements for manufacturers to develop, implement, and maintain processes applicable to all stages of the life-cycle of a medical device. Quality management system standards and risk management standards are good examples of process standards within the group standards type. Operation or maintenance of defibrillator standards are good examples of process standards within the product standards type. Because the focus can change at various points within the life-cycle of any given medical device, process standards are routinely developed both as group or product standards.

5.2 General approach to using standards

The essential principles of safety and performance are the general, high-level criteria that when met indicate that a medical device is safe and effective. Regulatory requirements expect that a medical device be safe and effective during its life-cycle and so conformity with the essential principles of safety and performance has to be achieved throughout the life-cycle of the medical device.

For the medical device manufacturer, this usually means that their medical device has to be

a) designed to be safe and effective, complying with the essential principles,

b) manufactured to maintain the design characteristics,

c) used in a way that maintains the design characteristics, and

d) in the case of findings while the medical device is in the post-production phase, there's a need to evaluate the production and post-production information for relevancy to safety and effectiveness and a redesign might be needed to make the medical device compliant again with the essential principles.

It is important to note that it's not possible to assure an acceptable level of safety and effectiveness in the life-cycle by simply being compliant with one or more standards at one time. A process for continuous compliance is required and the expectation is that this is achieved through the use of a quality management system and a risk management process (this is addressed in the general essential principles, 1 through 6, although the word risk management is not used there).

5.3 Risk management approach to demonstrating compliance

The first six essential principles are general and provide the criteria for risk management and are delineated in Table B.1. The rest of the essential principles, the design and manufacturing essential principles, can be viewed from a risk management perspective.

Generically, the design and manufacturing essential principles identify a general hazard and the expectancy of each can differ as

— the essential principles that identify the general expects that sequence or combinations of events leading to hazardous situations are identified and controlled if necessary,

— the essential principles identify a hazardous situation and require that the sequence or combination of events leading to the hazardous situation are identified and the risk is controlled if necessary, and

— the essential principles directly identify a risk control measure to be used to control the risk.

5.4 Phases of the medical device life-cycle

The medical device life-cycle includes all phases in the life of a medical device, from the initial conception to final decommissioning and disposal. During the medical device life-cycle, either process or product standards may be used to fulfil essential principles. Figure 2 depicts a sample life-cycle of a medical device, including examples of International Standards that may be utilized during the distinct phases of the life-cycle to meet the essential principles, and parallel process standards with distinct activities associated with each of the life-cycle phases.

Product standards generally define specific technical solutions to essential principles and are applied mainly during medical device design as possible technical solutions to essential principles. Those standards generally define requirements which, when implemented, provide risk control measures to known hazards and/or hazardous situations.

In addition, process standards detail requirements for processes, which exist continuously during the phases of a medical device life-cycle. These standards manage aspects of the medical device safety and performance as intended and thus assist the manufacturer in implementing the essential principles.

EXAMPLE 1 ISO 13485.

EXAMPLE 2 ISO 14971.

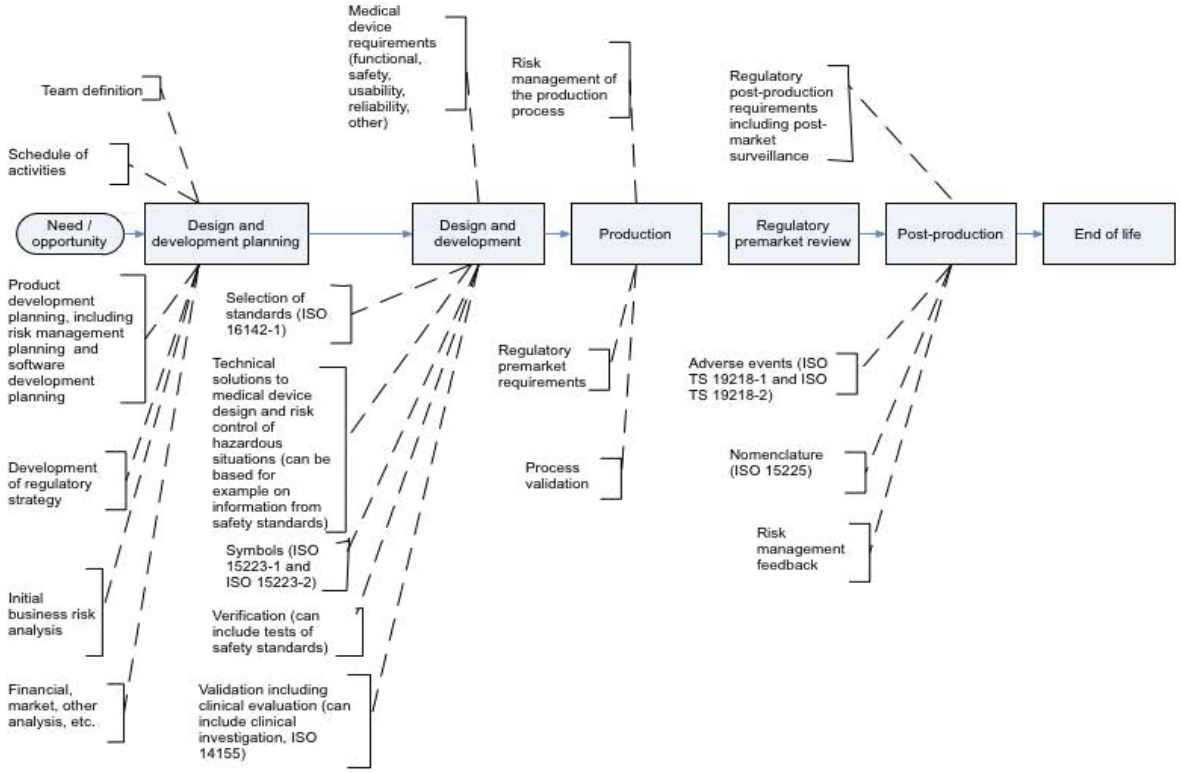

Figure 2 — Phases of the life-cycle

5.5 Use of standards during medical device life-cycle phases

5.5.1 Design and development planning

If a standard is intended to be used to demonstrate compliance with one or more essential principles, the requirements of the standard become requirements for the medical device in the early stages of the design process.

Several process standards, such as ISO 14971 on risk management, ISO 13485 on quality management systems, IEC 60601-1-9 on environmental impact (sustainability), IEC 62366-1 on usability, and IEC 62304 on software life-cycle processes require that plans are developed for each of those topics during the initial medical device design and development planning.

5.5.2 Design and development including testing and validation

As medical device design begins and product requirements are created, essential principles shall be incorporated as high-level product requirements. The manufacturer may use this part of ISO 16142 to guide the identification of standards to fulfil those essential principles. For example, in the case of electrical hazards, the technical solutions to the requirements of the IEC 60601 series are risk control measures that fulfil the requirements of the related essential principle. Testing to those requirements demonstrates that the risk control measure is implemented and the residual risk is acceptable.

Several other standards exist that may be used during this phase. For example, essential principle seven requires that a medical device has clinical evaluation as part of the compliance with the essential principles. One way to perform clinical evaluation is to perform clinical investigations, whereupon ISO 14155 may be used as requirement to perform this activity.

5.5.3 Regulatory pre-market review

During regulatory pre-market review, the standards used during the preceding life-cycle phases are identified and linked with the essential principles. This may be done by way of a checklist that links each essential principle to the technical solutions applied by the manufacturer with links to the applicable standards. The manufacturer should create a traceability matrix that links that checklist with the procedures, test reports and other records that demonstrate conformity with the essential principles.

5.5.4 Production

Several of the process standards are applicable to manufacturing. For example, ISO 13485 and ISO 14971 are applicable to manufacturing processes, the first with requirements to control the manufacturing process and the latter with requirements for risk management of the manufacturing processes. In addition, there are many group standards that are applicable to the manufacturing of medical devices that may be used to establish product or manufacturing specifications useful in fulfilling the essential principles.

EXAMPLE 1 Sterilization standards, ISO 11135, ISO 11137-1, ISO 11137-2, and ISO 11137-3.

EXAMPLE 2 Packaging, ISO 11607- series.

EXAMPLE 3 Environmental control standards, ISO 14644 and ISO 14698.

5.5.5 Post-production including medical device use and post-market surveillance

During post-production, the main objective of the manufacturer is to maintain safety and effectiveness by gathering information about the product use and feeding this information back into the quality management system, design development and risk management processes.

NOTE Standards such as ISO 19218[2] can be used as they define a code structure to facilitate this information gathering and communication.

5.5.6 End of life

End of life considerations shall be planned during medical device design. Hazardous waste, shelf life and obsolescence are all examples of considerations requiring attention.

End of life considerations such as environmental impacts are also beginning to be considered by regulators. Currently, there are few standards that deal directly with this aspect of the medical device life-cycle (for example, IEC 60601-1-9 on environmentally conscious design). There is an expectation that more standards will be developed in the future to deal with environmental impacts and, in particular, end of life considerations.

5.6 Assessing the conformity of a medical device

Conformity assessment is the systematic examination of records and procedures undertaken by the manufacturer, under requirements established by the authority having jurisdiction, to determine that a medical device conforms to the essential principles and is thereby safe and performs as intended by the manufacturer.

In assessing the conformity of a medical device with the essential principles, the manufacturer of a particular medical device may utilize standards or parts of several standards and combine them in a way that is considered to be appropriate for the medical device in question. The use of parts and/or combinations of standards should be acceptable for conformity assessment purposes.

Where available, specific product standards should be considered. When a product standard does not exist, consideration should be given to utilizing basic or group standards. Either way, if the combination of standards does not cover all the necessary essential principles of safety and performance for a specific medical device, other means of demonstrating conformance to the essential principles should

be used, such as the creation of valid scientific evidence for the medical device and essential principle in question. A manufacturer need not use an available standard and may create valid scientific evidence in lieu of using any standard to demonstrate conformance to the essential principles.

6 Essential principles and references to relevant standards and guides

6.1 Use of standards by authorities having jurisdiction

In some countries, authorities having jurisdiction acknowledge the use of voluntary consensus standards as one means of demonstrating compliance with relevant essential principles of safety and performance of medical devices. Standards suitable to address the essential principles should be based on

— a close relationship of the scope of the standard to one or more of the essential principles,

— the clarity and completeness of the technical requirements contained in the standard as it relates to a specific essential principle,

— the existence of test methods for determining compliance with each of the technical requirements in the standard, and

— the definition of clear acceptance criterion for determining that each technical requirement is met.

These standards should, wherever possible, be International Standards incorporating the thinking of the global marketplace.

The use of International Standards supports the development of consistent expectations between authorities having jurisdiction and manufacturers. In the absence of international consensus standards, it may be appropriate for authorities having jurisdiction to accept the use of regional or national consensus standards or industry standards.

Authorities having jurisdiction should establish and maintain a list of accepted standards that they find suitable for demonstrating conformance to these essential principles. Ideally, consensus standards should not be made mandatory and should be accepted and used without alteration whenever possible.

6.2 Manufacturers' use of essential principles and references to relevant standards or guides

Before placing a medical device on the market, a manufacturer shall establish that the applicable essential principles of safety and performance have been met in a satisfactory way. There may be a number of ways for a manufacturer to demonstrate compliance to essential principles.

The first six essential principles are general and provide criteria to ensure that a medical device

— is suitable for its intended use,

— achieves intended performance for its expected life time,

— follows good risk management principles and conforms to safety principles consistent with the current acknowledged state of the art,

— has risks associated with its use that are acceptable,

— is compatible with a high-level of protection of health and safety for people and the environment,

— provides benefits to the patient that outweighs any risks,

— follows good design, manufacture, and packaging principles, and

— is subject to clinical evaluation.

In Annex B, a number of significant standards are indicated that may be suitable for demonstrating compliance with specific parts of each related essential principle. The general essential principles, applicable to all medical devices including IVD medical devices, are listed in Table B.1. The additional essential principles for non-IVD medical devices are listed in Table B.2. When selecting standards from Annex B, it is important to consider the type of the medical device and process, as some standards listed relate to particular families of medical devices or processes (e.g. IEC 60601-1 relates to medical electrical equipment).

It is recognized that the requirements in a single standard typically do not meet all the specific parts of a given essential principle as related to a given medical device.

NOTE Other standards can be available, or under development, that can assist in demonstrating that such a medical device meets all the relevant essential principles.

The standards referenced in Annex B may be used as a starting point; however, they should be checked against a maintained source for the latest effective revision or version and the most recent publication should be used. Additionally, new or newly revised standards can have an annex that maps the requirements of the standard to the essential principles of this part of ISO 16142 and both should be considered.

There can be available standards not included in this part of ISO 16142 that may be used to meet a particular essential principle. Although the intent is to maintain this part of ISO 16142 on a routine basis, there will always be new standards that have not yet been considered and are therefore missing.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This Annex provides a rationale for some requirements of this part of ISO 16142 and is intended for those who are familiar with the subject of this part of ISO 16142 but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 16142 necessitated by those developments.

A.2 Types of references

A.2.1 General

Informative references give additional information intended to assist the understanding or use of a standard. They do not contain requirements and should be clear and provide useful information. Normative references contain requirements and are indispensable for conformance to a standard. The way in which normatively referenced information is cited determines the extent (whole or in part) to which the document applies.

The following subclauses are examples of standards referencing other standards.

A.2.2 Example of normative reference to a group standard

EXAMPLE The machine end of the tracheal tube connector shall be a male 15 mm conical connector complying with ISO 5356-1.

NOTE This example is taken from ISO 5361:—, 5.2.2.5.

A.2.3 Example of normative reference to a product standard

EXAMPLE Any breathing system filter, either incorporated into the ventilator or recommended for use with a ventilator, shall comply with the relevant requirements of ISO 23328-1 and ISO 23328-2.

NOTE This example is taken from ISO 80601-2-12:2011, 201.102.6.

A.2.4 Example of normative reference to identified requirements, clauses or subclauses

EXAMPLE The manufacturer shall identify user interface characteristics that could be related to safety as part of a risk analysis performed according to ISO 14971:2007, 4.2.

NOTE This example is adapted from IEC 62366-1:2015, 5.2.

A.2.5 Example of normative reference from a group standard to a basic standard

EXAMPLE Appliance couplers complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6.

NOTE This example is adapted from IEC 60601-1:2005, 8.11.3.4.

A.2.6 Example of specifying requirement(s) supported by informative reference to group standards

EXAMPLE The organization shall establish documented requirements for risk management throughout product realization. Records arising from risk management shall be maintained (see 4.2.4).

NOTE The example shown above is taken from ISO 13485:2003, 7.1.

A.3 Rationale for particular clauses and subclauses

The clauses and subclauses in this Annex have been numbered to correspond to the numbering of the clauses and subclauses of this part of ISO 16142 to which they refer. The numbering is therefore not consecutive.

Clause 1 Scope

This first edition of this part of ISO 16142 was developed as an International Standard and is intended to identify additional links between existing International Standards and essential principles of safety and performance of medical devices, other than IVD medical devices, as well as encourage and support global convergence of regulatory systems. It is intended for use by authorities having jurisdiction and manufacturers and provides benefits in establishing, in a consistent way, an economic and effective approach to the control of medical devices in the interest of public health.

Annex B
(normative)

Table relating essential principles to standards

B.1 General

The list of standards in Table B.1 and Table B.2 shall be considered as a starting point to determine which standards or which parts of a standard might be applicable to demonstrate conformance to the essential principles. Additional information regarding demonstration of conformance is found in 5.6. Not every standard in Table B.1 and Table B.2 is appropriate for any specific medical device and the manufacturer may disregard any standards that are not applicable. Any reference standards intended to be used should be checked against a maintained source for the latest effective revision.

Standards that are referenced for a major category of essential principles are potentially applicable to most if not all of the specific essential principles in the category. Where standards are limited to one or a few specific essential principles, references are made specific to the associated essential principle.

In this Annex, a number of significant standards are indicated which may be suitable for demonstrating compliance with certain features of the related essential principles. The standards chosen for this Annex are not all inclusive. Those identified are primarily International Standards and regional or national standards are only used when International Standards do not exist or could not be found. Many of the International Standards have regional or national adoptions that may be used. Other standards may be available, or under development, that can assist in demonstrating that a medical device meets all the relevant essential principles.

Other types of documents may be useful, in particular, for standards writers.

— ISO/IEC Guide 51.

— ISO/IEC Guide 63.

— IEC 60513.

For the purposes of this part of ISO 16142, foreseeable should be interpreted to mean reasonably foreseeable as it is used in ISO 14971 and other relevant standards.

B.2 Essential principles

Table B.1 contains the general principles for all medical devices. Table B.2 contains the additional principles for all non-IVD medical devices.

Table B.1 — General principles for all medical devices

Number	Essential principles of safety and performance of medical devices	References[a]
1	The medical device should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against benefits to the patient and are compatible with a high level of protection of health and safety. This shall include the following:	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
	a) reducing, as far as reasonably practicable and appropriate, the risk of use error due to the design of the medical device user interface and the environment in which the medical device is intended to be used (design for patient safety);	ISO 14971 IEC 62366-1 AAMI HE75
	b) consideration of the technical knowledge, experience, education and training and, where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	IEC 62366-1
2	The solutions adopted by the manufacturer for the design and manufacture of the medical device should conform to safety principles, taking into account the generally acknowledged state of the art. When risk reduction is required, the manufacturer should control the risks so that the residual risk associated with each hazard is judged acceptable. The manufacturer should apply the following principles in the priority order listed:	ISO 14971 ISO 13485 ISO/TR 14969 ISO 10993-1 ISO 7405 IEC/TR 80002-1 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
	a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60812
	b) eliminate risks as far as reasonably practicable through inherently safe design and manufacture;	ISO 14971 ISO 13485 ISO/TR 14969
	c) reduce as far as reasonably practicable the remaining risks by taking adequate protection measures, including alarms or information for safety;	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60601-1-8
	d) inform users of any residual risk.	ISO 14971 ISO 13485 ISO/TR 14969

[a] See also specific product standards in B.3.

Table B.1 *(continued)*

Number	Essential principles of safety and performance of medical devices	References[a]
3	The medical device should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that during normal conditions of use, they are suitable for their intended purpose.	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60601 (all parts) IEC/ISO 80601 (all parts) ISO 8828 ISO 9583 ISO 9584
4	The characteristics and performances referred to in essential principles 1, 2, and 3 should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the medical device, as indicated by the manufacturer, when the medical device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
5	The medical device should be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	ISO 14971 ISO 13485 ISO/TR 14969 IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 60601-1-11 IEC 60601-1-12
6	Any undesirable side-effect shall constitute an acceptable risk when weighed against the performances intended. All known and foreseeable risks, and any undesirable effects, should be minimized and be acceptable when weighed against the benefits of the intended performance of the medical device during normal conditions of use.	ISO 14971 ISO 13485 ISO/TR 14969 ISO 10993 (all parts) ISO 7405 IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 62366-1

[a] See also specific product standards in B.3.

Table B.2 — Additional principles for non-IVD medical devices

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
7	Clinical evaluation	
7.1	For all medical devices, a clinical evaluation is required. The clinical evaluation should review clinical data to establish that a favourable benefit-risk ratio exists for the medical device in the form of — clinical investigation reports, — literature reports/reviews, and — clinical experience.	ISO 14155
7.2	Clinical investigations on human subjects should be carried out in accordance with the spirit of the Helsinki Declaration. This includes every step in the clinical investigation from first consideration of the need and justification of the study to publication of the results. In addition, some countries may have specific regulatory requirements for pre-study protocol review or informed consent. NOTE Content and format of a clinical evaluation report is specific to the authority having jurisdiction.	ISO 14155
8	Chemical, physical, and biological properties	
8.1	The medical device should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in essential principles 1 through 6. Particular attention should be paid to the following:	
	a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability;	ISO/TR 14969 ISO 14630 ISO 10993-11 ISO 5832 (all parts) ISO 13779 (all parts) ISO 13782
	b) the compatibility between the materials used and biological tissues, cells, and body fluids taking account of the intended purpose of the medical device;	ISO 10993 (all parts) ISO 7405 ISO 14630 ISO 5832 (all parts) ISO 13779 (all parts) ISO 13782
	c) the choice of materials used reflecting, where appropriate, matters such as hardness, wear and fatigue strength;	ISO 14630 IEC 60601 (all parts) IEC/ISO 80601 (all parts) ISO 5832 (all parts) ISO 5834 (all parts) ISO 6474-1 ISO 7153-1 ISO 13779 (all parts) ISO 13782

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
	d) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand.	ISO 14630
8.2	The medical device should be designed, manufactured and packaged in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the medical device and to the patients, taking account the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of the exposure.	ISO/TR 14969 ISO 10993 (all parts) ISO 7405 ISO 11607 (all parts)
8.3	The medical device should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures. If the medical device is intended to administer medicinal products, they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and their performance and is maintained in accordance with the intended use.	ISO 14971 ISO 10993 (all parts) ISO 11607 (all parts) IEC 60601 (all parts) IEC/ISO 80601 (all parts) ISO 13402 ISO 14971
8.4	The medical device should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the medical device. Special attention should be given to substances which are carcinogenic, mutagenic or toxic to reproduction.	ISO 14971 ISO 10993 (all parts) ISO 7405 ISO 11607 (all parts) IEC 60601 (all parts) IEC/ISO 80601 (all parts) ISO 5834 (all parts)
8.5	The medical device should be designed and manufactured in such a way as to reduce, as far as reasonably practicable and appropriate risks posed by the unintentional ingress or egress of substances into or from the medical device taking into account the medical device and the nature of the environment in which it is intended to be used.	ISO 14971 ISO 10993 (all parts) ISO 7405 ISO 13402
9	Infection and microbial contamination	
9.1	The medical devices and manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, other persons. The design should:	ISO 10993 (all parts) ISO 7405 ISO 14971
	a) allow easy handling, and, where necessary,	
	b) reduce as far as reasonably practicable and appropriate any microbial leakage from the medical device and/or microbial exposure during use, and	ISO 23328 (all parts)
	c) prevent microbial contamination of the medical device or specimen, where applicable, by the patient, user or other person.	ISO 23328 (all parts)

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
9.2	Medical devices labelled as having a special microbiological state should be designed, manufactured and packaged to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.	ISO 15985 ISO 10993-11 ISO 11737 (all parts)
9.3	Medical devices delivered in a sterile state should be designed, manufactured and packaged in a non-reusable pack, and/or according to appropriate procedures, to ensure they are sterile when placed on the market and remain sterile, under the transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.	ISO 11607 (all parts) ISO 11135 (all parts) ISO 11137 (all parts) ISO 11138 (all parts) ISO 11140 (all parts) ISO/TS 13004 ISO 13408 (all parts) ISO 14160 ISO 14161 ISO 14937 ISO 15882 ISO 15883 (all parts) ISO 17664 ISO 25424
9.4	Medical devices labelled either as sterile or as having a special microbiological state should have been processed, manufactured and, if applicable, sterilized by appropriate, validated methods.	ISO/TS 13004 ISO 13408 (all parts) ISO 14160 ISO 14161 ISO 14937 ISO 15883 (all parts) ISO 17664 ISO 17665-1 ISO 18472 ISO 20857
9.5	Medical devices intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	ISO 14644 (all parts) ISO 14698 (all parts)
9.6	Packaging systems for non-sterile medical devices should maintain the integrity and cleanliness of the product.	ISO 17664 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
9.7	If the medical devices are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account the method of sterilization indicated by the manufacturer.	ISO 10993 (all parts) ISO 7405 ISO 11607 (all parts)
9.8	The labelling of the medical device should distinguish between identical or similar products sold in both sterile and non-sterile conditions.	ISO 15223-1 ISO 80601 (all parts)

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
10	Medical devices incorporating a substance considered to be a medicinal product/drug These essential principles are not intended to provide guidance on combination products as a whole since definitions have yet to be harmonized and practice varies between different jurisdictions.	
10.1	Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product/drug as defined in the relevant legislation that applies in that jurisdiction and which is liable to act upon the body with action ancillary to that of the medical device, the safety, quality and performance of the medical device as a whole should be verified, as well as the safety, quality and efficacy of the substance in the specific application.	
10.2	When considering combination products as described in essential principle 10.1, the non-medical device aspects (e.g. substance, human blood derivative, ancillary substance) shall be assessed according to the requirements of the relevant authority having jurisdiction.	
11	Medical devices incorporating materials of biological origin	
11.1	In some jurisdictions, products incorporating tissues, cells and substances of animal origin may be considered medical devices. In this case, such tissue, cells and substances should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. National regulations may require that the manufacturer and/or the authority having jurisdiction maintain the information and the geographical origin of the animals. Processing, preservation, testing and handling of the tissue, cells and substances of animal origin should be carried out so as to provide optimal safety for patients, users and, by applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	ISO 22442 (all parts) ASTM F2027 ASTM F2212
11.2	In some jurisdictions, products incorporating human tissues, cells and substances may be considered medical devices. In this case, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	ISO 22442 (all parts) ASTM F2027 ASTM F2212
11.3	In some jurisdictions, products incorporating cells and substances of microbial origin may be considered medical devices. In this case processing, preservation, testing and handling of cells and substances should be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.	ISO 22442 (all parts) ASTM F2027 ASTM F2212
12	Environmental properties	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
12.1	If the medical device is intended for use in combination with other medical devices or equipment the whole combination, including the connection system should be safe and should not impair the specified performance of the medical device. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks from incorrect connection.	IEC 60601 (all parts) IEC/ISO 80601 (all parts) ISO 80369 (all parts) ISO/IEEE 11073 (all parts) ASTM F2761 ISO 14971 ISO 5356 (all parts) ISO 5359 ISO 21969 IEC 80001-1 IEC/TR 80001-2-1
12.2	The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate	ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
	a) the risks of injury to the patient, user or other persons in connection with their physical and ergonomic features,	IEC 62366-1 IEC 60601-1-6
	b) the risks of use error due to the design of the medical device user interface and the environment in which the medical device is intended to be used,	IEC 62366-1 IEC 60601-1-6 AAMI HE75
	c) the risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature or variations in pressure and acceleration,	IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-12
	d) the risks associated with the use of the medical device when it comes into contact with materials, liquids, and gases to which it is exposed during normal conditions of use,	IEC 60601 (all parts) and IEC/ISO 80601 (all parts) ISO 13402
	e) the risks associated with possible negative interaction between software and the environment within which it operates and interacts,	IEC 60601-1 IEC 62304 ISO/IEEE 11073 (all parts)
	f) the risks of accidental penetration of substances into the medical device,	
	g) the risks of reciprocal interference with other medical devices normally used in the investigations or for the treatment given, and	ISO/IEEE 11073 (all parts) IEC 60601-1-2
	h) the risks arising where maintenance or calibration are not possible (as with implants) from aging of materials used or loss of accuracy of any measuring or control mechanism.	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
12.4	The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to a medical device whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.	ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
12.5	The medical device should be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.	IEC 60601 (all parts) IEC/ISO 80601 (all parts)
12.6	The medical device should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	IEC 60601-1-9
13	Medical devices with a diagnostic or measuring function	
13.1	A diagnostic medical device or a medical device with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the medical device, based on appropriate scientific and technical methods.	ISO/IEEE 11073 (all parts) IEC 60601-1 (all parts) IEC/ISO 80601-2 (all parts)
13.2	The limits of accuracy should be indicated by the manufacturer.	IEC 60601 (all parts) IEC/ISO 80601 (all parts)
13.3	Any measurement, monitoring and display scale should be designed in line with ergonomic principles, taking into account the intended purpose of the medical device.	IEC 60601-1-6 IEC 62366-1 AAMI HE75
13.4	Whenever possible values expressed numerically should be in commonly accepted, standardized units, and understood by users of the medical device. While generally supporting the convergence on the global use of internationally standardized measurement units, considerations of safety, user familiarity and established clinical practice may justify the use of other recognized measurement units.	IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 60601-1-6 IEC 62366-1 IEC 80000 IEC 80003
14	Protection against radiation	
14.1	General:	
	The medical device should be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation should be reduced as far as reasonably practicable and be appropriate for the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 60601-1-3 IEC 60336 IEC 60522 IEC 60627 IEC 61217 IEC 60825 IEC 62471
14.2	Intended radiation:	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
	a) Where a medical device is designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it should be possible for the user to control the emissions. Such a medical device should be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.	IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 60601-1-3 IEC 60825 IEC 61217 IEC 62471
	b) Where a medical device is intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where reasonably practicable, with visual displays and/or audible warnings of such emissions.	IEC 60825 IEC 62471
14.3	Unintended radiation:	
	The medical device should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as reasonably practicable and appropriate.	IEC 60601-1
14.4	Instructions for use:	
	The operating instructions for a medical device emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	IEC 60601-1 IEC 61910-1
14.5	Ionizing radiation:	
	a) A medical device intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where reasonably practicable and appropriate, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.	IEC 60601-1-3 IEC 60336 IEC 60522 IEC 60627
	b) A medical device emitting ionizing radiation intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.	IEC 60601-1-3 IEC 60336 IEC 60522 IEC 60627 IEC 62220 (all parts) IEC 62494-1
	c) A medical device emitting ionizing radiation, intended for therapeutic radiology, should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose, the beam type and energy and where appropriate the energy distribution of the radiation beam.	IEC 60580 IEC 61217
15	Medical devices that incorporate software and software as a medical device	
15.1	A medical device incorporating electronic programmable systems, including software, or software that is a medical device itself, should be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequential risks.	IEC 60601-1 IEC 62304 ISO/IEC 15026 (all parts)

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
15.2	For a medical device which incorporates software or for software that is a medical device itself, the software shall be validated according to the state of the art taking into account the principles of development life-cycle, risk management, verification and validation.	IEC 60601-1 IEC 62304 ISO/IEC 15026 (all parts)
16	Active medical devices and devices connected to the medical devices	
16.1	For an active medical device, in the event of a single fault condition, appropriate means should be adopted to eliminate or reduce as far as reasonably practicable and appropriate consequential risks.	ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
16.2	The medical device, where the safety of the patient depends on an internal power supply, should be equipped with a means of determining the state of the power supply.	
16.3	The medical device, where the safety of the patient depends on an external power supply, should include an alarm system to signal any power failure.	
16.4	The medical device, intended to monitor one or more clinical parameters of a patient, should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	
16.5	The medical device should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other medical devices or equipment in the usual environment.	IEC 60601-1-2
16.6	The medical device should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	IEC 60601-1-2
16.7	The medical device should be designed and manufactured in such a way as to avoid, as far as reasonably practicable and appropriate, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the medical device and in the event of a single fault condition in the medical device, provided that the medical device is installed and maintained as indicated by the manufacturer.	ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
17	Protection against mechanical risks	
17.1	The medical device should be designed and manufactured in such a way as to protect the patient and user against mechanical risks for example, connected with resistance to movement, instability and moving parts.	ISO 14630 ISO 16061 ISO 14971 IEC 60601 (all parts) and IEC/ISO 80601 (all parts)
17.2	The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks arising from vibration generated by the medical device, taking into account technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	ISO 14630 ISO 16061 ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
17.3	The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks arising from the noise emitted, taking account technical progress and the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	ISO 14630 ISO 16061 ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
17.4	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate risks.	ISO 14630 ISO 16061 ISO 14971 ISO 80369 (all parts) IEC 60601 (all parts) IEC/ISO 80601 (all parts) ISO 5356 (all parts) ISO 5359
17.5	The medical device should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate, the risk of error when certain parts within the medical device are intended to be connected or reconnected before or during use.	ISO 14630 ISO 16061 ISO 80369-(series) ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 62366-1 ISO 5356 (all parts) ISO 5359 ISO 21969
17.6	Accessible parts of the medical device (excluding the parts or areas intended to supply heat or reach given temperatures) and its surroundings should not attain potentially dangerous temperatures under normal conditions of use.	ISO 14630 ISO 16061 ISO 14971 IEC 60601 (all parts) IEC/ISO 80601 (all parts)
18	Protection against the risks posed to the patient by energy supplies or substances	
18.1	A medical device for supplying the patient with energy or substances should be designed and manufactured in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.	IEC 60601 (all parts) IEC/ISO 80601 (all parts)
18.2	The medical device should be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. The medical device should incorporate suitable means to prevent, as far as reasonably practicable and appropriate, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.	IEC 60601 (all parts) IEC/ISO 80601 (all parts)
19	Controls and indicators	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
19.1	The function of the controls and indicators should be clearly specified on the medical device.	IEC 60601 (all parts) IEC/ISO 80601 (all parts)
19.2	Where the medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.	IEC 60601 (all parts) IEC/ISO 80601 (all parts) IEC 60601-1-6 IEC 62366-1 AAMI HE75
20	Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons	
20.1	A medical device for use by lay persons should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from the variation that can be reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer should be easy for the lay person to understand and apply.	IEC 60601-1-6 IEC 60601-1-11 IEC 62366-1 AAMI HE75
20.2	A medical device for use by lay persons should be designed and manufactured in such a way as to remove or reduce as far as reasonably practicable and appropriate the risk of error during use by the lay person in the handling of the medical device and also in the interpretation of results.	IEC 60601-1-6 IEC 60601-1-11 IEC 62366-1 AAMI HE75
20.3	A medical device for use by lay persons should, as far as reasonably practicable and appropriate, include a procedure by which the lay person can verify that, at the time of use, the product will perform as intended by the manufacturer.	IEC 60601-1-6 IEC 60601-1-11 IEC 62366-1 AAMI HE75
21	Label and instructions for use	
21.1	Each medical device should be accompanied by the information needed to use it safely and properly, and to ensure the intended performance, taking into account the training and knowledge of the potential users and to identify the manufacturer of the medical device. This information comprises the details and the data on the label and in the instructions for use. All this information should be easily understood.	ISO/TR 24971
21.2	If the intended purpose of the medical device is not obvious to the user, the manufacturer shall clearly state it on the label and in the instructions for use.	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
21.3	As far as practicable and appropriate, the information needed to use the medical device safely shall be set out on the medical device itself. If not practicable and appropriate, the information shall be on the individual packaging. If the medical device is not individually packaged, .the information shallbe set out in the leaflet supplied with one or more medical devices. Instructions for use shall be included in the packaging for every medical device. Alternatively, this information may be provided through other methods that meet the requirements of authorities having jurisdiction, such as electronic instructions for use. However, depending on the type of medical device, a subset of information may be required to be directly available for safe use. By way of exception, no such instructions for use are needed for a medical device if it can be used safely without any such instructions.	ISO/TR 24971 IEC 60601-1 (all parts)
21.4	Where appropriate, this information should take the form of symbols. Any symbol or identification colour used shall conform to the relevant international standards. The symbols and colours shall be described in the documentation supplied with the medical device.	ISO 7000 ISO 7010 ISO 15223-1 IEC 60417 IEC 60878
21.5	The label shall meet the requirements of the authority having jurisdiction and contain the following particulars:	EN 1041
	a) the name or trade name and address of the manufacturer and where the manufacturer does not have an address within the locale, an authorized representative within the locale, to which the user can refer;	
	b) the details strictly necessary to identify the medical device and the contents of the packaging especially for the users;	
	c) where appropriate, the word “sterile”;	ISO 17664
	d) where appropriate, the batch code, preceded by the word “LOT”, or the serial number;	EN 1041
	e) where appropriate, an indication of the date by which the medical device should be used (e.g. expiration date), in safety, expressed as the year and month;	
	f) where appropriate, an indication that the medical device is for single use. A manufacturer’s indication of single use shall be consistent;	
	g) if the medical device is custom-made, the words “custom-made device” or follow n) below;	
	h) if the medical device is intended for clinical investigations, the words “exclusively for clinical investigations” or follow n) below;	
	i) any special storage and/or handling conditions;	
	j) any special operating instructions;	
	k) any warnings and/or precautions to take;	
	l) year of manufacture for an active medical device other than that covered by e). This indication may be included in the batch or serial number;	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
	m) where applicable, method of sterilization;	ISO 17664
	n) where applicable, other requirements from authorities having jurisdiction. EXAMPLES Global Medical Device Nomenclature (GMDN), Unique Device Identifier (UDI), and Universal Medical Device Nomenclature System (UMDNS).	
21.6	Wherever reasonable and practicable, the medical device and detachable components shall be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the medical device and detachable components.	
21.7	Where appropriate, the instructions for use shall contain the following particulars:	ISO/TR 24971 AAMI TIR49 EN 1041
	a) the name or trade name and address of the manufacturer and where the manufacturer does not have an address within the locale, an authorized representative within the locale, to which the user can refer;	
	b) the details strictly necessary to identify the medical device and the contents of the packaging especially for the users;	ISO 17664
	c) where appropriate, the word “STERILE”;	ISO 17664
	d) where appropriate, an indication that the medical device is for single use. A manufacturer’s indication of single use shall be consistent;	
	e) if the medical device is custom-made, the words “custom-made device” or follow t) below;	
	f) if the medical device is intended for clinical investigations, the words “exclusively for clinical investigations” or follow t) below;	
	g) any special storage and/or handling conditions;	
	h) any special operating instructions;	
	i) any warnings and/or precautions to take;	
	j) where applicable, method of sterilization;	
	k) if the medical device shall be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct medical devices or equipment to use in order to obtain a safe combination;	
	l) all the information needed to verify whether the medical device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the medical device operate properly and safely at all times;	
	m) where appropriate, information to avoid certain risks in connection with implantation of the medical device;	
	n) information regarding the risks of reciprocal interference posed by the presence of the medical device during specific investigations or treatment;	

[a] See also specific product standards in B.3.

Table B.2 *(continued)*

Number	Essential principles of safety and performance of non-IVD medical devices	References[a]
	o) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	ISO 17664
	p) if the medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilization of the medical device to be resterilized, and any restriction on the number of reuses. Where the medical device is supplied with the intention that it be sterilized before use, the instructions for cleaning and sterilization shall be such that, if correctly followed, the medical device will still comply with the requirements in essential principles 1 through 7. If in accordance with essential principle 21.3 no instructions for use are needed, the information shall be made available to the user upon request;	ISO 17664
	q) details of any further treatment or handling needed before the medical device can be used (for example, sterilization, final assembly, etc.);	ISO 17664
	r) in the case of a medical device emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation;	
	s) where applicable, other requirements from authorities having jurisdiction.	
21.8	The date of issue or revision of the instructions for use relevant to the particular medical device.	
21.9	The instructions for use shall also include details allowing the medical staff to brief the patient on any contraindications and any precautions to be taken for a medical device intended to be used by a lay person. These details should cover in particular:	AAMI TIR49 EN 1041
	a) precautions to be taken in the event of changes in the performance of the medical device;	
	b) precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	
	c) adequate information regarding the medicinal product or products which the medical device in question is designed to administer, including any limitations in the choice of substances to be delivered;	
	d) precautions to be taken against any special, unusual risks related to the disposal of the medical device;	
	e) medicinal substances, or human blood derivatives incorporated into the medical device as an integral part in accordance with essential principle 10.1;	
	f) degree of accuracy claimed for a medical device with a measuring function.	

[a] See also specific product standards in B.3.

B.3 Additional specific product standards

The following specific product standards address the essential principles:

— ISO 1135 (all parts);

— ISO 3107;

— ISO 3826 (all parts);

— ISO 5360;

— ISO 5361;

— ISO 5362;

— ISO 5364;

— ISO 5366 (all parts);

— ISO 5367;

— ISO 5838 (all parts);

— ISO 5840 (all parts);

— ISO 5841 (all parts);

— ISO 7197;

— ISO 7198;

— ISO 7199;

— ISO 7206 (all parts);

— ISO 7207 (all parts);

— ISO 7376;

— ISO 7396 (all parts);

— ISO 7494 (all parts);

— ISO 7864;

— ISO 7886 (all parts);

— ISO 8185;

— ISO 8536 (all parts);

— ISO 8537;

— ISO 8637;

— ISO 8638;

— ISO 8827;

— ISO 8835-7;

— ISO 9168;

— ISO 9170 (all parts);

— ISO 9360 (all parts);
— ISO 9626;
— ISO 9713;
— ISO 10079 (all parts);
— ISO 10524 (all parts);
— ISO 10555 (all parts);
— ISO 10651 (all parts);
— ISO 11040 (all parts);
— ISO 11197;
— ISO 11318;
— ISO 11608 (all parts);
— ISO 11663;
— ISO 13958;
— ISO 13959;
— ISO 14242 (all parts);
— ISO 14243 (all parts);
— ISO 14408;
— ISO 14457;
— ISO 14602;
— ISO 14607;
— ISO 14708 (all parts);
— ISO 14879;
— ISO 15001;
— ISO 15002;
— ISO 17510;
— ISO 18777;
— ISO 18778;
— ISO 19054;
— ISO 21534;
— ISO 21535;
— ISO 21536;
— ISO 21649;
— ISO 22523;

— ISO 22610;

— ISO 22612;

— ISO 22675;

— ISO 23500;

— ISO 25539 (all parts);

— ISO 23747;

— ISO 23907;

— ISO 23908;

— ISO 26722;

— ISO 27186;

— IEC 60118-15;

— IEC 60731;

— IEC 60976;

— IEC 61168;

— IEC 61223-2-6;

— IEC 61223-3;

— IEC 61303;

— IEC 61391 (all parts);

— IEC 61674;

— IEC 61676;

— IEC 61689;

— IEC 61846;

— IEC 61847;

— IEC 62083;

— IEC 62266;

— IEC 62359;

— IEC 62563-1;

— ISO 81060 (all parts).

Annex C
(informative)

Website listings of other standards suitable for the medical device sector and for assessment purposes

The following websites contain lists of standards authorities with jurisdiction have been found suitable for the medical device sector and for assessment purposes:

— http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm

— http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

— http://www.tga.gov.au/standards-orders-and-medical-devices

— http://www.hc-sc.gc.ca/dhp-mps/md-im/index-eng.php

— http://www.jisc.go.jp/eng/index.html

Annex D
(informative)

Reference to the essential principles by International Standards

D.1 Purpose

Writers of standards in the healthcare sector are encouraged to use the essential principles to help ensure that their standard addresses the appropriate high-level requirements such that a medical device, which complies with their standard, will provide an appropriate level of safety and clinical effectiveness. Standards that fulfil the high-level requirements of the essential principles should include an informative annex that maps the clauses and subclauses of the standard to the corresponding specific essential requirements that they fulfil. D.2 is a template for such an annex for writers of standards where the relevant clause/subclause numbers are entered in the second column of Table D.1 and any relevant qualifying remark or notes are added in the third column of the table. Rows that are not applicable should be deleted. The title of the annex should be "Reference to the essential principles".

D.2 Suggested format for a reference to the essential principles annex

This International Standard has been prepared to support the essential principles of safety and performance of (insert type of medical device, process or service here) as a medical device according to ISO 16142-1:2015. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1:2015. Other means are possible. Table D.1 maps the clauses and subclauses of this document with the **essential principles** of ISO 16142-1:2015.

Table D.1 — Correspondence between the essential principles and this International Standard

Essential principle of ISO 16142-1:2015	**Corresponding clause(s)/subclause(s) of this International Standard**	**Qualifying remarks/Notes**
1	[list the relevant clauses and subclauses of the standard being mapped in this column]	[indicate if this relevant essential principle is only partially covered in this column]
a)		
b)		
2		
a)		
b)		
c)		
d)		
3		
4		
5		
6		
7.1		
7.2		
8.1		
a)		
b)		
c)		
d)		
8.2		
8.3		
8.4		
8.5		
9.1		
a)		
b)		
c)		
9.2		
9.3		
9.4		
9.5		
9.6		
9.7		
9.8		
10.1		
10.2		
11.1		
11.2		
11.3		
12.1		
12.2		
a)		

Table D.1 *(continued)*

Essential principle of ISO 16142-1:2015	**Corresponding clause(s)/subclause(s) of this International Standard**	**Qualifying remarks/Notes**
b)		
c)		
d)		
e)		
f)		
g)		
h)		
12.4		
12.5		
12.6		
13.1		
13.2		
13.3		
13.4		
14.1		
14.2 a)		
14.2 b)		
14.3		
14.4		
14.5 a)		
14.5 b)		
14.5 c)		
15.1		
15.2		
16.1		
16.2		
16.3		
16.4		
16.5		
16.6		
16.7		
17.1		
17.2		
17.3		
17.4		
17.5		
17.6		
18.1		
18.2		
19.1		
19.2		
20.1		
20.2		

Table D.1 *(continued)*

Essential principle of ISO 16142-1:2015	**Corresponding clause(s)/subclause(s) of this International Standard**	**Qualifying remarks/Notes**
20.3		
21.1		
21.2		
21.3		
21.4		
21.5		
a)		
b)		
c)		
d)		
e)		
f)		
g)		
h)		
i)		
j)		
k)		
l)		
m)		
n)		
21.6		
21.7		
a)		
b)		
c)		
d)		
e)		
f)		
g)		
h)		
i)		
j)		
k)		
l)		
m)		
n)		
o)		
p)		
q)		
r)		
s)		
t)		
21.8		

Table D.1 *(continued)*

Essential principle of ISO 16142-1:2015	**Corresponding clause(s)/subclause(s) of this International Standard**	**Qualifying remarks/Notes**
21.9		
a)		
b)		
c)		
d)		
e)		
f)		

Annex E
(informative)

Terminology — alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP) provides access to terms and definitions[2)].

Term	Source
authority having jurisdiction	3.1
basic standard	3.2
essential principles	3.3
essential principles of safety and performance	3.3
group standard	3.4
hazard	3.5
hazardous situation	3.6
informative	3.7
intended use	3.8
IVD medical device	3.9
life-cycle	3.10
manufacturer	3.11
medical device	3.12
normative	3.13
process standard	3.14
product standard	3.15
post-production	3.16
risk	3.17
risk control	3.18
risk management	3.19
state of the art	3.20

2) Available at: https://www.iso.org/obp/ui/#home.

Bibliography

[1] ISO 690, *Information and documentation — Guidelines for bibliographic references and citations to information resources*

[2] ISO/TS 19218-1, *Medical devices — Hierarchical coding structure for adverse events — Part 1: Event-type codes*

[3] ISO/IEC Guide 51, *Safety aspects — Guidelines for their inclusion in standards*

[4] ISO/IEC Guide 63, *Guide to the development and inclusion of safety aspects in International Standards for medical devices*

[5] Global Harmonization Task Force — Study Group 1. *Essential principles of safety and performance of medical devices*[3)]

[6] Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/883/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, 2012-09-26

3) The Global Harmonization Task Force (GHTF) has been dissolved and replaced by the International Medical Device Regulators Forum (IMDRF). www.imdrf.org.

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