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Medical devices — Recognized essential principles of safety and performance of medical devices —

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

Dispositifs médicaux — Principes essentiels reconnus de sécurité et de performance des dispositifs médicaux —

Partie 2: Principes essentiels généraux et principes essentiels spécifiques supplémentaires pour tous les dispositifs médicaux de DIV et directives sur le choix des normes

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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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This document builds on ISO 16142-1, which cancels and replaces ISO/TR 16142:2006.

A list of all parts in the ISO 16142 series can be found on the ISO website.

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 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 risk 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 were 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 16142:2006, 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 document, 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: italics.

In this document, 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 document, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this document,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document,

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

— “must” is used to describe an external constraint, but is not mandatory for compliance with this document.

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.

Medical devices — Recognized essential principles of safety and performance of medical devices —

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

1 Scope

This document, 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 document identifies and describes the six general essential principles of safety and performance (see Table B.1) that apply to all medical devices, including IVD medical devices (*in vitro* diagnostic).

This document 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 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 document 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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 2859 (all parts), *Sampling procedures for inspection by attributes*

ISO 3951 (all parts), *Sampling procedures for inspection by variables*

ISO 11135, *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 11607 (all parts), *Packaging for terminally sterilized medical devices*

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

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

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

ISO 14644 (all parts), *Cleanrooms and associated controlled environments*

ISO 14698 (all parts), *Cleanrooms and associated controlled environments — Biocontamination control*

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

ISO 15193, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for content and presentation of reference measurement procedures*

ISO 15194, *In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation*

ISO 15195, *Laboratory medicine — Requirements for reference measurement laboratories*

ISO 15197, *In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus*

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 16269 (all parts), *Statistical interpretation of data*

ISO 17511, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 17593, *Clinical laboratory testing and in vitro medical devices — Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy*

ISO 17665 (all parts), *Sterilization of health care products — Moist heat*

ISO 18113 (all parts), *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)*

ISO 18153, *In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials*

ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test 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 22442 (all parts), *Medical devices utilizing animal tissues and their derivatives*

ISO 23640, *In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents*

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

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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

CLSI EP05[1)], *Evaluation of precision of quantitative measurement procedures; Approved guideline*

CLSI EP06[1)], *Evaluation of the linearity of quantitative measurement procedures: a statistical approach; Approved guideline*

CLSI EP07[1)], *Interference testing in clinical chemistry; Approved guideline*

CLSI EP12-A2[1)], *User protocol for evaluation of qualitative test performance; Approved guideline*

CLSI EP26-A[1)], *User evaluation of between-reagent lot variation; Approved guideline*

CLSI POCT12[1)], *Human point-of-care blood glucose testing in acute and chronic care facilities; Approved guideline*

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

ASTM F2027, *Standard guide for characterization and testing of raw or starting biomaterials for tissue-engineered medical products*

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*

EN 13532, *General requirements for in vitro diagnostic medical devices for self-testing*

EN 13612, *Performance evaluation of in vitro diagnostic medical devices*

EN 13641, *Elimination or reduction of risk of infection related to in vitro diagnostic reagents*

EN 14136, *Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures*

IEC 60068, *Environmental testing*

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

IEC 60825 (all parts), *Safety of laser products*

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

IEC 61010-2-101, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment*

IEC 61326-2-6, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment*

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

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

IEC 62366-2, *Medical devices — Part 2: Guidance on the application of usability engineering to medical devices*

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

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

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

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1) Available from: Clinical and Laboratory Standards Institute, Wayne, PA US.

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 80001-2-5, *Application of risk management for IT-networks incorporating medical devices — Part 2-5: Application guidance — Guidance on distributed alarm systems*

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

Note For convenience, the sources of all defined terms used in this document 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* (3.13) is safe and performs as intended

3.4
group standard
basic standard (3.2) that specifies safety and performance requirements 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 is/are exposed to one or more *hazards* (3.5)

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

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* (3.12)

[SOURCE: ISO 14971:2007, 2.5]

3.9
IVD kit
IVD medical device kit
set of reactive components that are packaged together and intended to be used to perform a specific IVD examination

Note 1 to entry: IVD kit components can include reagents (such as antibodies, enzymes, buffer and diluents), calibrators, controls and other articles and materials.

[SOURCE: ISO 18113-1:2009, 3.32, modified]

3.10
***in vitro* diagnostic medical device**
*** IVD medical device**
medical device (3.13) intended by the *manufacturer* (3.12) 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: An IVD medical device can be used alone or in combination with accessories or other medical devices.

[SOURCE: ISO 14971:2007, 2.6, modified]

3.11
life-cycle
all phases in the life of a *medical device* (3.13), from the initial conception to final decommissioning and disposal

[SOURCE: ISO 14971:2007, 2.7]

3.12
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of a *medical device* (3.13), assembling a system, or adapting a *medical device* (3.13) 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 13485:2016, 3.8.

[SOURCE: ISO 14971:2007, 2.8]

3.13
medical device
any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the *manufacturer* (3.12) 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,

— 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),

— disinfection substances,

— 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 use* (3.9) should be subject to this document.

[SOURCE: ISO 14971:2007, 2.9, modified — The word "intended purpose" has been changed to "intended use".]

3.14
normative
providing required information

Note 1 to entry: Required for compliance.

3.15
performance evaluation
investigation of a device intended to become an *IVD medical device* (3.10) for the purpose of establishing or verifying its performance claims

[SOURCE: ISO 18113-1:2009, 3.52]

3.16
process standard
standard that specifies requirements for elements of a process used to develop, implement or maintain a stage of the *life-cycle* (3.11) of a product or service

Note 1 to entry: A process standard may be a *basic standard* (3.2), *group standard* (3.4) or *product standard* (3.17).

3.17
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* (3.2) and *group standards* (3.4)

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

3.18
post-production
part of the *life-cycle* (3.11) of the product after the design has been completed and the *medical device* (3.13) has been manufactured

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

[SOURCE: ISO 14971:2007, 2.11]

3.19
residual risk
risk (3.20) remaining after *risk control* (3.21) measures have been taken

Note 1 to entry: Adapted from ISO/IEC Guide 51:2014, 3.9.

Note 2 to entry: ISO/IEC Guide 51:2014, 3.9 uses the term "protective measures" rather than "risk control measures." However, in the context of this document, "protective measures" are only one option for controlling risk as described in 6.2.

[SOURCE: ISO 14971:2007, 2.15]

3.20
risk
combination of the probability of occurrence of harm and the severity of that harm

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

3.21
risk control
process in which decisions are made and measures implemented by which *risks* (3.20) are reduced to, or maintained within, specified levels

[SOURCE: ISO 14971:2007, 2.19]

3.22
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.20)

[SOURCE: ISO 14971:2007, 2.22]

3.23
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 IVD medical devices

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

IVD 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 an IVD medical device carries out its use(s) as intended by its manufacturer. For some IVD medical devices, medical benefit or clinical effectiveness can only be determined by conducting clinical performance studies carried out in human subjects.

The manufacturer of an IVD medical device is expected to design and manufacture a product that is safe and clinically effective throughout its life-cycle. This document describes fundamental design and manufacturing criteria, referred to as essential principles of safety and performance, to ensure this outcome. This document is structured to provide general essential principles that apply to all medical devices including IVD medical devices. This document also includes additional essential principles of safety and performance which are relevant to 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 IVD medical devices, ensuring their safety and performance. The concept of essential principles was developed by Study Group 1 of the Global Harmonization Task Force[5]. The concept is intended to encourage convergence in the evolution of regulatory systems for IVD medical devices.

NOTE Some authorities having 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 premarket and post-market requirements throughout the life-cycle of IVD medical devices.

Every IVD medical device has a use as intended by its manufacturer. An IVD medical device is clinically effective when it provides accurate and reliable information for diagnostic, monitoring or compatibility purposes 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 IVD 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 General approach to using standards

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

For the IVD medical device manufacturer, this usually means that their IVD medical device complies with the essential principles and must be

a) designed to be safe and effective,

b) manufactured to maintain the design characteristics,

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

d) in the post-production phase, reviewed to evaluate the production and post-production information for relevancy to safety and performance, in which case, a design change might be needed to make the IVD medical device compliant again with the essential principles.

It is important to note that it is not possible to ensure an acceptable level of safety and performance 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 to 6, although the word risk management is not used there).

5.2 Types of standards useful to demonstrate compliance

Basic standards, group standards, product standards and process standards are the four types of consensus standards, any of which can be normative. 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).

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.

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.

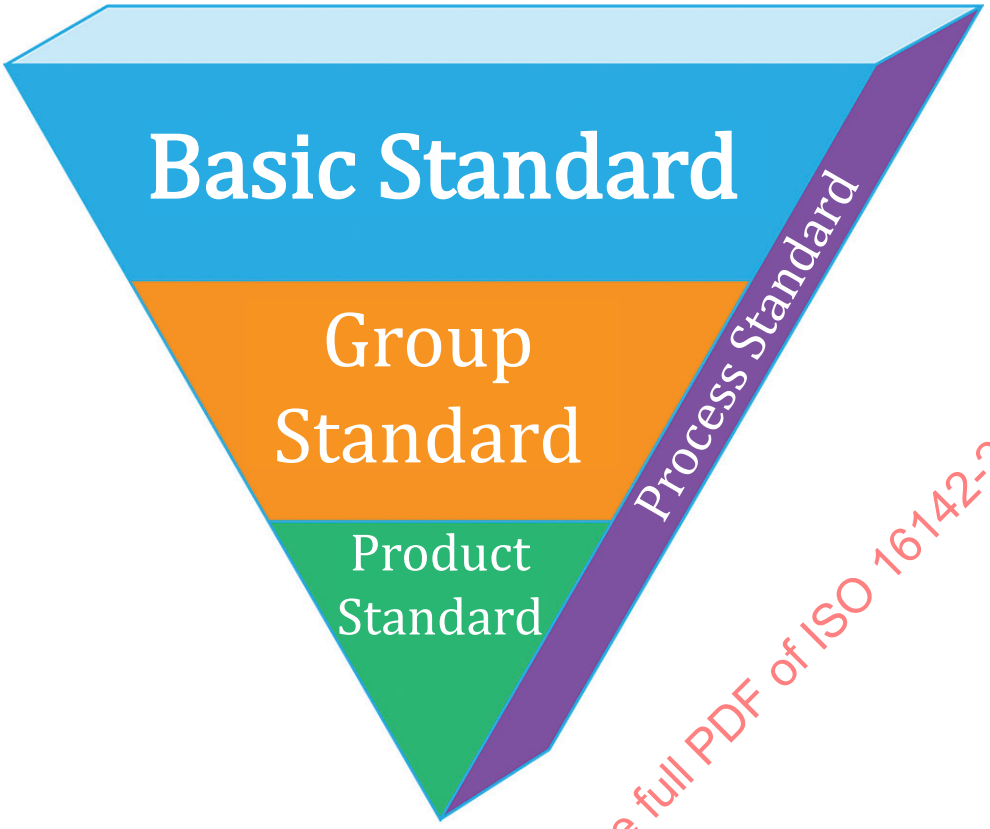

Figure 1 — Types of standards

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 blood glucose test strips and meter. 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 blood glucose monitoring systems is a good example of a process standard 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.

5.3 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 identify the general aspects that the 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;

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

5.4 Phases of the IVD 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 IVD 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 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.

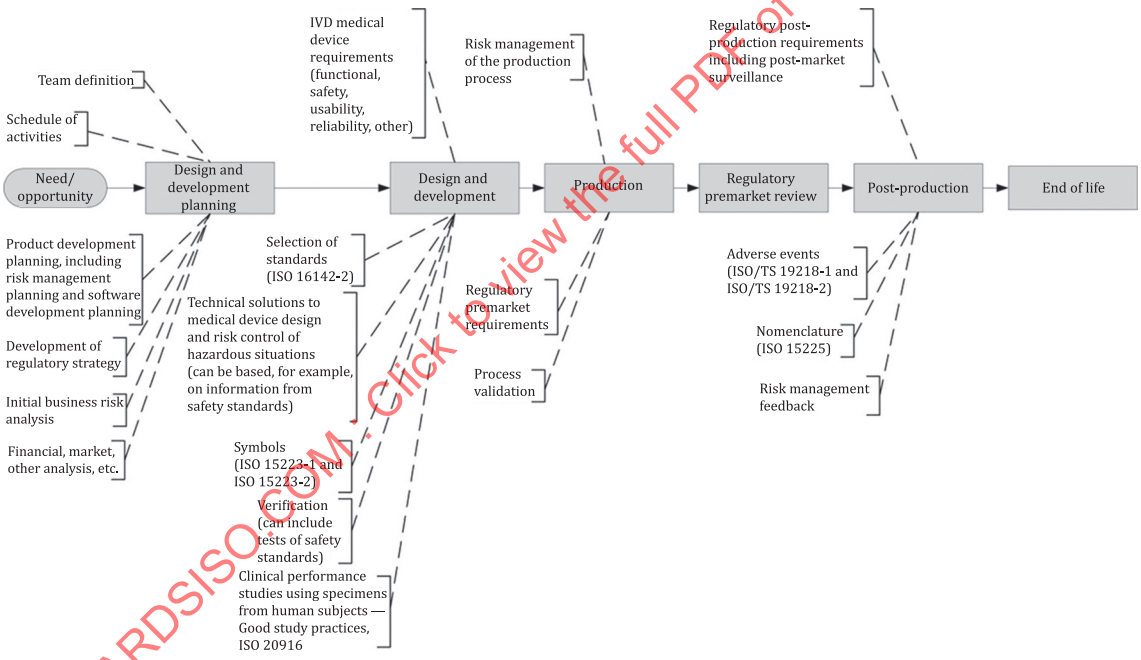

Figure 2 — Phases of the life-cycle

5.5 Use of standards during IVD 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 IVD 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 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 IVD medical device design and development planning.

NOTE Although this document does not apply to IVD medical device, manufacturers can find useful information in IEC 60601-1-9[12] on environmental impact (sustainability).

5.5.2 Design and development including testing and validation

As IVD medical device design begins and product requirements are created, essential principles shall be incorporated as high-level product criteria. The manufacturer may use this document 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 61010[13] 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 an IVD medical device has performance evaluation as part of the compliance with the essential principles. One way to conduct a performance evaluation is to perform investigations, whereupon ISO 20916 may be used as requirements to perform this activity.

5.5.3 Regulatory premarket review

During regulatory premarket 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 IVD medical devices that may be used to establish product or manufacturing specifications useful in fulfilling the essential principles.

EXAMPLE 1 Calibration standard (ISO 17511).

EXAMPLE 2 Labelling [ISO 18113 (all parts)].

EXAMPLE 3 Stability standard (ISO 23640).

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

During post-production, the main objective of the manufacturer is to maintain safety and performance 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/TS 19218-1 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 IVD medical

device life-cycle. 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.

NOTE Although IEC 60601-1-9[12] is not intended to apply to an IVD medical device, manufacturers can find useful information on the reduction of environmental impact (sustainability) in this document.

5.6 Assessing the conformity of an IVD 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 an IVD medical device conforms to the essential principles and is thereby safe and performs as intended by the manufacturer.

In assessing the conformity of an IVD medical device with the essential principles, the manufacturer of a particular IVD medical device may utilize standards or parts of several standards and combine them in a way that is considered to be appropriate for the IVD medical device in question. The use of parts 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 IVD medical device, other means of demonstrating conformance to the essential principles should be used, such as the creation of valid scientific evidence for the IVD 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 IVD 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. Annex C contains lists of standards authorities with jurisdiction found suitable for the IVD medical device sector and for assessment purposes.

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

Before placing an IVD 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 (see Table B.1) are general and provide the following criteria to ensure that a medical device (including an IVD medical device):

— is suitable for its intended use;

— achieves intended performance for its expected lifetime;

— 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 performance 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 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 61010-2-101 relates to IVD medical devices).

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 IVD medical device.

The standards referenced in Annex B shall 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 document and both should be considered.

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

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

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document 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 document 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 requirements specified in ISO 17511 pertaining to calibration and metrological traceability apply.

NOTE This example is taken from ISO 15197:2013, 4.2.

A.2.3 Example of normative reference to a product standard

EXAMPLE Stability of reagents and control materials through the expiration dates shall be demonstrated. The requirements specified in ISO 23640 apply.

NOTE This example is taken from ISO 17593:2007, 6.13.

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 Detachable mains supply cords with mains connectors according to IEC 60320[16] shall either meet the requirements of IEC 60799[17] or shall be rated at least for the current rating of the mains connector fitted to the cord.

NOTE This example is adapted from IEC 61010-1:2010, 6.10.1.

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

EXAMPLE The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5).

NOTE This example is taken from ISO 13485:2016, 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 document to which they refer. The numbering is, therefore, not consecutive.

Clause 1 Scope

This first edition of this document 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 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 IVD medical devices in the interest of public health.

Definition 3.10 IVD medical device

The definition of IVD medical device includes so called companion IVD medical devices (e.g. those intended to determine whether a specific treatment is suitable for the patient). Largely, standards for such IVD medical devices have yet to be written.

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 IVD 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 an IVD 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.

For the purposes of this document, 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 IVD medical devices.

Table B.1 — General principles for all medical devices

Essential principle 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, it 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 its 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	ISO 13485 ISO 14971 IEC 61010-2-101
	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), and	AAMI HE75 ISO 14971 IEC 62366-1 IEC 62366-2
	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 IEC 62366-2
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 13485 ISO 14971 IEC 61010-2-101 IEC 80002-1
	a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;	ISO 13485 ISO 14971 ISO/TR 24971 IEC 60812
	b) eliminate risks, as far as reasonably practicable, through inherently safe design and manufacture;	ISO 13485 ISO 14971
	c) reduce, as far as reasonably practicable, the remaining risks by taking adequate protection measures, including alarms or information for safety; and	ISO 13485 ISO 14971 ISO/TR 24971 IEC 61010-2-101
	d) inform users of any residual risk.	ISO 13485 ISO 14971 ISO/TR 24971
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, it is suitable for its intended use.	EN 13612 EN 13975 ISO 13485 ISO 14971 IEC 61010-2-101

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

Table B.1 *(continued)*

Essential principle number	Essential principles of safety and performance of medical devices	References[a]
4	The characteristics and performance 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.	CLSI EP26 EN 14136 ISO 13485 ISO 14971 ISO 23640 IEC 61010-2-101
5	The medical device should be designed, manufactured and packaged in such a way that its characteristics and performance during its 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 13485 ISO 14971 ISO 23640 IEC 61010-2-101
6	Any undesirable side-effect must constitute an acceptable risk when weighed against the performance 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 13485 ISO 14971 IEC 61010-2-101 IEC 62366-1 IEC 62366-2
[a] See also specific product standards in B.3.		

Table B.2 — Additional principles for IVD medical devices

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
7	Performance evaluation including analytical performance and, where appropriate, clinical performance	
7.1	For an IVD medical device, a performance evaluation should be conducted. The performance evaluation should review analytical performance data and, where appropriate, clinical performance data in the form of any — scientific, peer-reviewed literature, — performance study reports, and — experience gained by routine diagnostic testing to establish that the IVD medical device achieves its intended performance during normal conditions of use and that the known and foreseeable risks, and any undesirable effects, are minimized and acceptable when weighed against the benefits of the intended performance.	CLSI EP05 CLSI EP06 CLSI EP07 CLSI EP09 CLSI EP12 CLSI EP17 CLSI POCT12 EN 13612 EN 14136 ISO 14971 ISO 17511 ISO 18153
7.2	Clinical performance studies using specimens from human subjects should be carried out in accordance with the spirit of the Declaration of Helsinki. This includes every step in the clinical performance study 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 informed consent. NOTE Content and format of a performance evaluation report is specific to the authority having jurisdiction.	EN 13612
8	Chemical, physical and biological properties	
[a] See also specific product standards in B.3.		

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
8.1	The IVD medical device should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in essential principle 6. Particular attention should be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens or analyte (measurand) to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of its intended use.	EN 13532 ISO 13485 ISO 14971
8.2	The IVD 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 IVD medical device and to patients, taking account of the intended use of the IVD medical device.	ISO 13485 EN 13532 ISO 14971
8.3	The IVD 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 IVD medical device. Special attention should be given to substances, which are carcinogenic, mutagenic or toxic to reproduction.	ISO 13485 EN 13532 ISO 14971
8.4	The IVD 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 the unintentional ingress or egress of substances into or from the IVD medical device taking into account the IVD medical device and the nature of the environment in which it is intended to be used.	ISO 13485 EN 13532 ISO 14971 IEC 61010-2-101
9	Infection and microbial contamination	
9.1	The IVD medical device 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 user, professional or lay, or, where applicable, other person. The design should:	EN 13641 ISO 14971 IEC 62366-1 IEC 62366-2
	a) allow easy and safe handling, and, where necessary,	IEC 62366-1 IEC 62366-2
	b) reduce, as far as reasonably practicable and appropriate, any microbial leakage from the IVD medical device or microbial exposure during use, and	EN 13641 ISO 14971 IEC 62366-1 IEC 62366-2
	c) prevent microbial contamination of the IVD medical device or specimen, where applicable, by the user, professional or lay or other person.	ISO 11607 (all parts) ISO 14971 IEC 62366-1 IEC 62366-2
9.2	The IVD medical device labelled either as sterile or as having a special microbiological state should be designed, manufactured and packaged to ensure it remains so when placed on the market and remains so under the transport and storage conditions specified by the manufacturer until the protective packaging is damaged or opened.	ISO 11607 (all parts) EN 13641 ISO 14644 (all parts) ISO 14698 (all parts)

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
9.3	The IVD medical device 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 11135 (all parts) ISO 11137 (all parts) ISO 11138 (all parts) ISO 11140 (all parts) ISO 11607 (all parts) ISO 11737 (all parts) ISO/TS 13004 ISO 13408 (all parts) ISO 14161 ISO 14644 (all parts) ISO 14698 (all parts) ISO 14937 ISO 15882 ISO 17665 (all parts) ISO 18472 ISO 20857 ISO 25424
9.4	The IVD medical device intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	ISO 14644 (all parts) ISO 14698 (all parts) ISO 11607 (all parts)
9.5	Packaging systems for a non-sterile IVD medical device should maintain the integrity and cleanliness of the IVD medical device.	
10	IVD medical devices incorporating materials of biological origin 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 the IVD medical device include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of animal origin should be carried out to provide optimal safety for user, professional or lay, or other person.	ASTM F2027 EN 13641 ISO 22442 (all parts)
10.2	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. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended use of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device. National regulations may require that the manufacturer or the authority having jurisdiction retain information on the geographical origin of the animals.	ASTM F2027 EN 13641 ISO 22442 (all parts)

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
10.3	Where an IVD medical device includes human tissues, cells and substances, the selection of sources, donors or substances of human origin, processing, preservation, testing and handling of tissues, cells and substances of such origin should be carried out to provide optimal safety for user, professional or lay, or other person. 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. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended use of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.	ASTM F2027 EN 13641 ISO 22442 (all parts)
10.4	Where an IVD medical device includes cells and substances of microbial origin, the processing, preservation, testing and handling of cells and substances should be carried out to provide optimal safety for user, professional or lay, or other person. 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. This may not apply to certain IVD medical devices if the activity of the virus and other transmissible agent are integral to the intended use of the IVD medical device or when such elimination or inactivation process would compromise the performance of the IVD medical device.	ASTM F2027 EN 13641 ISO 22442 (all parts)
11	Environmental properties	
11.1	If the IVD medical device is intended for use in combination with other medical devices or equipment, the whole combination, including the connection system should not impair the specified performance of the medical devices. Any restrictions on use applying to such combinations should be indicated on the label or in the instructions for use.	ASTM F2027 ISO 18113 (all parts) ISO 22442 (all parts)

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
11.2	The IVD medical device should be designed and manufactured in such a way as to remove or reduce, as far as reasonably practicable and appropriate, the following:	ASTM F2761 ISO 14971 ISO/IEEE 11073 (all parts) IEC 61010-2-101 IEC/ISO 80001-1 IEC/TR 80001-2-1
	a) the risk of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;	ISO 14971
	b) the risk of use error due to the ergonomic features, human factors and the environment in which the IVD medical device is intended to be used;	ISO 14971 IEC 62366-1 IEC 62366-2
	c) the risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations thereof;	AAMI HE75 ISO 14971 IEC 61010-2-101 IEC 61326-2-6 IEC 62366-1 IEC 62366-2
	d) the risks associated with the use of the IVD medical device when it comes into contact with materials, liquids and gases to which it is exposed during normal conditions of use;	ISO 14971 IEC 61010-2–101
	e) the risk associated with the possible negative interaction between software and the environment within which it operates and interacts;	ASTM F2761 ISO/IEEE 11073 (all parts) ISO 14971 IEC 62304 IEC/ISO 80001-1 IEC/ISO 80002-1 IEC 82304-1
	f) the risks of accidental penetration of substances into the IVD medical device;	ISO 14971 IEC 61010-2-101
	g) the risk of incorrect identification of specimens/samples; and	ISO 14971
	h) the risks of reasonably foreseeable interference with other medical devices such as carry over between IVD medical devices.	AAMI HE75 ISO 14971 IEC 61326-2-6 IEC 61010-2-101 IEC 62366-1 IEC 62366-2
11.3	The IVD medical device should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to an IVD medical device whose intended use includes exposure to or use in association with flammable substances or substances that could promote combustion.	ISO 14971 IEC 61010-2-101
11.4	The IVD medical device should be designed and manufactured in such a way that adjustment, calibration and maintenance, where such is necessary to achieve the performance intended, can be done safely.	AAMI HE75 ISO 14971 IEC 61010-2-101 IEC 62366-1 IEC 62366-2

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
11.5	The IVD medical device should be designed and manufactured in such a way as to facilitate the safe disposal of any waste substances.	ISO 14971 IEC 61010-2-101
12	Performance characteristics	
12.1	The IVD medical device should be designed and manufactured in such a way that the performance characteristics support the intended use based on appropriate scientific and technical methods. In particular, where appropriate, the design should address sensitivity, specificity, accuracy, which results from trueness (bias) and precision (repeatability and reproducibility), control of known relevant interferences and limits of detection. These performance characteristics need to be maintained during the lifetime of the IVD medical device as indicated by the manufacturer.	CLSI EP05 CLSI EP06 CLSI EP07 CLSI EP09 CLSI EP12 CLSI EP17 CLSI POCT12 EN 13612 EN 13975 ISO 2859 ISO 3951 ISO 15193 ISO 15194 ISO 15195 ISO 15197 ISO 16269 (all parts) ISO/IEC 17025 ISO 17511 ISO 17593 ISO 18153 ISO 23640
12.2	Where the performance of an IVD medical device depends on the use of calibrators or control materials, the traceability of values assigned to such calibrators or control materials should be ensured through available reference measurement procedures or available reference materials of a higher order.	CLSI EP14 ISO 15193 ISO 15194 ISO 15195 ISO/IEC 17025 ISO 17511 ISO 18153
12.3	Wherever possible, values expressed numerically should be in commonly accepted, standardized units and understood by the users of the IVD medical device.	IEC 62366-1 IEC 62366-2 IEC 80000 (all parts)
13	Protection against radiation	
13.1	The IVD medical device should be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other person to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as reasonably practicable and appropriate.	IEC 60825 (all parts) IEC 61326-2-6 IEC 62471
13.2	When the IVD medical device is intended to emit potentially hazardous, visible or invisible radiation, it should as far as reasonably practicable and appropriate be:	
	a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled or adjusted; and	IEC 60825 (all parts) IEC 62471
	b) fitted with visual displays or audible warnings of such emissions.	IEC/TR 80001-2-5
14	IVD medical devices that incorporate software and standalone IVD medical device software	

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
14.1	For the IVD medical device, which incorporates software or for standalone software that is an IVD medical device in 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.	ISO/IEC 15026 (all parts) IEC 62304 IEC 82304-1
15	IVD medical devices connected to, or equipped with, an energy source	
15.1	The IVD medical device, where the safety of the patient depends on an internal power supply in the IVD medical device, should be equipped with a means of determining the state of the power supply.	ISO 14971
15.2	The IVD 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 61326-2-6
15.3	The IVD 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 61326-2-6
15.4	The IVD medical device should be designed and manufactured in such a way as to avoid, as far as reasonably practicable, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the IVD medical device and in the event of a single fault condition in the IVD medical device, provided the IVD medical device is installed and maintained as indicated by the manufacturer.	IEC 61010-2-101
16	Protection against mechanical and thermal risks	
16.1	The IVD medical device should be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks connected with, for example, resistance to movement, instability and moving parts.	ISO 14971 IEC 61010-2-101
16.2	Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection means shall be incorporated.	ISO 14971 IEC 61010-2-101
16.3	The IVD medical device should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from vibration generated by the IVD medical device, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	ISO 14971 IEC 60068 (all parts)
16.4	The IVD medical device should be designed and manufactured in such a way as to reduce to the lowest practicable level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise particularly at source.	ISO 14971
16.5	Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person should handle should be designed and constructed in such a way as to minimize all possible risks.	ISO 14971 IEC 61010-2-101

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
16.6	The IVD medical device should be designed and manufactured in such a way as to reduce to the lowest practicable level the risk of error when certain parts within the IVD medical device are intended to be connected or reconnected before or during use.	ISO 14971 IEC 61010-2-101 IEC 62366-1 IEC 62366-2
16.7	Accessible parts of the IVD medical device (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings should not attain potentially dangerous temperatures under normal use.	IEC 61010-2–101
17	Protection against the risks posed by IVD medical devices for self-testing	
17.1	The IVD medical device for self-testing should be designed and manufactured in such a way that it performs appropriately for its intended use taking into account the skills and the means available to lay persons and the influence resulting from variation that can 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.	AAMI HE75 EN 13532 EN 13612 ISO 15197 ISO 17593 ISO 18113-1 ISO 18113-4 ISO 18113-5 IEC 62366-1 IEC 62366-2
17.2	The IVD medical device for self-testing should be designed and manufactured in such a way as to reduce, as far as reasonably practicable, the risk of use error by the lay person in the handling of the IVD medical device and, if applicable, the specimen, and also in the interpretation of results.	IEC 62366-1 IEC 62366-2
17.3	The IVD medical device for self-testing should, where reasonably possible, 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.	ISO 18113-1 ISO 18113-4 ISO 18113-5 IEC 62366-1 IEC 62366-2
18	General requirements regarding the information supplied by the manufacturer	
18.1	Each IVD medical device shall be accompanied by the information needed to identify the IVD medical device and its manufacturer and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. This information should be easily understood. Such information may appear on the IVD medical device itself, on the packaging or in the instructions for use. The accompanying information shall meet the requirements of the authority having jurisdiction and contain the following particulars.	ISO 14971 ISO 15223-1 ISO 18113 (all parts) ISO/TR 24971 IEC 60878 IEC 61010-2-101 IEC 62366-1 IEC 62366-2
	a) The medium, format, content, legibility and location of the label and instructions for use shall be appropriate to the particular IVD medical device, its intended use and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some IVD medical devices may include separate information for the professional user and the lay person.	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 62366-1 IEC 62366-2

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
	b) The information required on the label, shall be provided on the IVD medical device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit or on the packaging of multiple IVD medical devices. Where multiple IVD medical devices are supplied to a single user or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	c) In duly justified and exceptional cases, instructions for use may not be needed or may be abbreviated if the IVD medical device can be used safely and as intended by the manufacturer without any such instructions for use.	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 62366-1 IEC 62366-2
	d) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	ISO 18113 (all parts)
	e) When the IVD medical device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the IVD medical device is intended for near-patient testing.	ISO 18113 (all parts)
	f) Residual risks, which are required to be communicated to the user or other person, shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.	ISO 14971 ISO 18113 (all parts) IEC 62366-1 IEC 62366-2
	g) Where appropriate, this information should take the form of internationally recognized symbols. Any symbol or identification colour used shall conform to the accepted standards. The symbols and colours shall be described in the documentation supplied with the IVD medical device.	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	h) In the case of an IVD medical device containing a substance or a mixture which can be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements shall apply. Where there is insufficient space to put all the information on the IVD medical device itself, the relevant hazard pictograms shall be put on the label and the other information required by that regulation shall be given in the instructions for use.	ISO 18113 (all parts) IEC 61010-2-101
	i) The provisions on the safety data sheet for any substance or mixtures shall apply unless all relevant information as appropriate is already made available by the instructions for use.	
	j) For a reagent derived from biological material, the source and, where applicable, a measure of its activity.	ISO 18113 (all parts)
18.2	The label shall meet the requirements of the authority having jurisdiction and contain the following particulars:	ISO 18113 (all parts)
	a) the name or trade name of the IVD medical device;	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
	b) the details strictly necessary for the user to identify the IVD medical device and, where it is not obvious for the user, the intended use of the IVD medical device;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	c) 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;	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	d) an indication that the IVD medical device is for *in vitro* diagnostic use;	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	e) the batch code/lot number or the serial number of the IVD medical device and separate components preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate, or the equivalent;	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	f) where applicable, the unique device identification (UDI);	
	g) an unambiguous indication of the date until when the IVD medical device, or any of its components, may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order, or where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	h) where relevant, an indication of the net quantity of contents, expressed in terms of weight, concentration, volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;	ISO 18113 (all parts)
	i) an indication of any special storage or handling condition that applies;	ISO 18113 (all parts)
	j) where appropriate, an indication of the sterile state of the IVD medical device and the sterilization method or a statement indicating any special microbiological state or state of cleanliness;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	k) warnings or precautions to be taken that need to be brought to the immediate attention of the user, professional or lay, or other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use;	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	l) where applicable, any particular operating instructions;	ISO 18113 (all parts) IEC 61010-2-101
	m) if the IVD medical device is intended for single use or single-patient use, an indication of that fact. A manufacturer's indication of single use or single-patient use shall be consistent for a model or type reference;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	n) if the IVD medical device is intended for self-testing or near-patient testing, an indication of that fact;	ISO 18113 (all parts) IEC 61010-2-101
	o) if the IVD medical device is for "performance evaluation only", an indication of that fact; and NOTE The actual text of the indication is authority having jurisdiction-specific.	ISO 18113 (all parts)

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
	p) where an IVD medical device kit includes individual reagents and articles that can be made available as a separate IVD medical device, each such IVD medical device shall comply with the labelling requirements contained 18.2.	ISO 18113 (all parts)
18.3	The instructions for use shall meet the requirements of the authority having jurisdiction and contain the following particulars:	ISO 18113 (all parts)
	a) the name or trade name of the IVD medical device;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	b) the IVD medical device's intended use:	ISO 18113 (all parts)
	i) what is detected or measured and whether it is qualitative, quantitative or a combination of both,	ISO 18113 (all parts)
	ii) the operating principle,	ISO 18113 (all parts)
	iii) its function (e.g. screening, monitoring, diagnosis or support of diagnosis),	ISO 18113 (all parts)
	iv) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate,	ISO 18113 (all parts)
	v) the type of specimen(s) required,	ISO 18113 (all parts)
	vi) the intended user and intended patient population, and	ISO 18113 (all parts)
	vii) the use environment;	ISO 18113 (all parts)
	c) an indication that the IVD medical device is for *in vitro* diagnostic use;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	d) a description of the test principle;	ISO 18113 (all parts)
	e) instructions from reception of the specimen to obtaining and analysing results to ensure that the IVD medical device performs as intended (e.g. calibration, quality control, cleaning and disinfection);	ISO 18113 (all parts)
	f) a description of the reagents, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only) if applicable;	ISO 18113 (all parts)
	g) a list of materials provided and a list of special materials or equipment required but not provided;	ISO 18113 (all parts)
	h) for IVD medical devices intended for use together with other medical devices, including IVD medical devices, or equipment:	
	i) information to identify such IVD medical devices or equipment, in order to obtain a safe combination, or	
	ii) information on any known restrictions to combinations of medical devices, including IVD medical devices, and equipment;	
	i) an indication of any storage (e.g. temperature, light, humidity, dust) or handling conditions which apply;	ISO 18113 (all parts) IEC 61010-2-101
	j) an indication of any operating (e.g. temperature, light, humidity, dust) or handling conditions which apply;	ISO 18113 (all parts) IEC 61010-2-101
	k) where relevant, any change in the shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions;	ISO 18113 (all parts)

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
	l) if the IVD medical device is supplied as sterile, an indication of its sterile state, the sterilization method and instructions in the event of the sterile packaging being damaged before use;	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	m) information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the IVD medical device. This information shall cover, where appropriate:	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	i) warnings, precautions or measures to be taken in the event of malfunction of the IVD medical device or its degradation as suggested by changes in its appearance that may affect performance,	ISO 18113 (all parts) IEC 61010-2-101
	ii) warnings, precautions or measures to be taken in regard to the exposure to 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 or temperature,	ISO 18113 (all parts) IEC 61010-2-101 IEC 61326-2-6
	iii) warnings, precautions or measures to be taken in regard to the risks of interference posed by the reasonably foreseeable presence of the IVD medical device during diagnostic procedures, evaluations or therapeutic treatments (e.g. electromagnetic interference emitted by the IVD medical device affecting other equipment),	ISO 18113 (all parts) IEC 61010-2-101 IEC 61326-2-6
	iv) precautions related to materials incorporated into the IVD medical device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitization or allergic reaction of the patient or user,	
	v) if the IVD medical device is intended for single use or single-patient use, an indication of that fact. A manufacturer's indication of single use or single-patient use shall be consistent for a model or type reference, and	ISO 15223-1 ISO 18113 (all parts) IEC 60878
	vi) if the IVD medical device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the IVD medical device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses;	
	n) any warnings or precautions related to potentially infectious material that is included in the IVD medical device;	ISO 18113 (all parts)
	o) where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety) or particular qualifications of the IVD medical device intended user;	IEC 61010-2-101
	p) conditions for collection, handling and preparation of the specimen including additive and preservatives necessary to maintain the integrity of the specimen and recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen, if appropriate;	ISO 18113 (all parts)

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
	q) details of any preparatory treatment or handling of the IVD medical device before it is ready for use (e.g. sterilization, final assembly, calibration, etc.);	ISO 18113 (all parts) IEC 61010-2-101
	r) the information needed to verify whether the IVD medical device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:	ISO 18113 (all parts) IEC 61010-2-101
	i) details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection,	IEC 61010-2-101
	ii) identification of any consumable components and how to replace them,	ISO 18113 (all parts) IEC 61010-2-101
	iii) information on any necessary calibration to ensure that the IVD medical device operates properly and safely during its intended lifetime, and	ISO 17511 ISO 18113 (all parts) ISO 18153
	iv) methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing the IVD medical device;	IEC 61010-2-101
	s) where relevant, recommendations for quality control procedures;	ISO 18113 (all parts)
	t) the metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials or reference measurement procedures of higher order;	ISO 17511 ISO 18113 (all parts)
	u) assay procedure including calculations and interpretation of results and where relevant, if any, confirmatory testing is necessary;	ISO 18113 (all parts)
	v) performance characteristics, to the extent necessary for the IVD medical device to be used safely and effectively [e.g. clinical sensitivity, clinical specificity, positive predictive value, negative predictive value, accuracy which results from trueness (bias) and precision (repeatability, reproducibility), limits of detection and measurement range, including information needed for the control of known relevant interferences, limitations of the method and information about the use of available reference measurement procedures and materials by the user];	ISO 17511 ISO 18113 (all parts)
	w) where relevant, reference intervals;	ISO 18113 (all parts)
	x) information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that can affect the performance of the IVD medical device;	ISO 18113 (all parts)
	y) warnings or precautions to be taken in order to facilitate the safe disposal of the IVD medical device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:	ISO 18113 (all parts) IEC 61010-2-101
	i) infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin),	ISO 18113 (all parts) IEC 61010-2-101
	ii) environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation), and	IEC 61010-2-101
	iii) physical hazards (e.g. explosion);	IEC 61010-2-101

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

Table B.2 *(continued)*

Essential principle number	Essential principles of safety and performance of IVD medical devices	References[a]
	z) the name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number or fax number or website address to obtain technical assistance;	ISO 15223-1 ISO 18113 (all parts) IEC 60878 IEC 61010-2-101
	aa) date of issue or revision of the instructions for use relevant to the particular IVD medical device;	ISO 18113 (all parts)
	bb) a notice to the user, professional or lay, that any serious incident that has occurred in relation to the IVD medical device should be reported to the manufacturer and the authority having jurisdiction where the IVD medical device was purchased or used; and	
	cc) where an IVD medical device kit includes individual reagents and articles that can be made available as separate IVD medical devices, each such IVD medical device shall comply with the labelling requirements contained in 18.3.	ISO 18113 (all parts)
18.4	In addition, the instructions for use for the IVD medical device intended for self-testing or near-patient testing shall comply with the following:	
	a) details of the test procedure, including any reagent preparation, specimen collection or preparation and information on how to run the test and read the results;	ISO 15197 ISO 17593 ISO 18113-1 ISO 18113-4 ISO 18113-5
	b) the results need to be expressed and presented in a way that is readily understood by the intended user;	ISO 15197 ISO 17593 ISO 18113-1 ISO 18113-4 ISO 18113-5 IEC 62366-1 IEC 62366-2
	c) information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false-negative result. Information shall also be provided as to any factors that can affect the test result (e.g. age, gender, menstruation, infection, exercise, fasting, diet or medication);	ISO 15197 ISO 17593 ISO 18113-1 ISO 18113-4
	d) for the IVD medical device intended for self-testing, the information provided shall include a statement clearly directing that the user should not take any decision of medical relevance without first consulting the appropriate healthcare professional; and	ISO 15197 ISO 17593 ISO 18113-1 ISO 18113-4
	e) for the IVD medical device intended for self-testing used for the monitoring of an existing disease, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.	ISO 15197 ISO 17593 ISO 18113-1 ISO 18113-4

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

B.3 Additional specific product standards

The following specific product standards can support the essential principles, but have not been mapped to Table B.1 or Table B.2:

— CLSI POCT04-A2[20];

— CLSI MMO3-Ed3[21];

— CLSI MM06-A2[22];

— CLSI MM09-A2[23];

— CLSI MM12-A[24];

— CLSI MM16-A[25];

— CLSI MM17-A[26];

— CLSI MM22-A[27];

— CLSI M53-A[28];

— CLSI I/LA18-A2[29];

— ISO 5725 (all parts)[2];

— ISO 16256[6];

— ISO 16355 (all parts) [4];

— ISO 22870[19].

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 found suitable for the IVD medical device sector and for assessment purposes:

— https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

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

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

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

— http://www.nicpbp.org.cn/qxbgzx/CL0490/