INTERNATIONAL STANDARD

ISO 16142-1

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

Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

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

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

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Foreword

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

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

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

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

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

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

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

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

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

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

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

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

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

ISO 16142 consists of the following parts, under the general title *Medical devices — Recognized essential principles of safety and performance of medical devices*:

— *Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

The following parts are under preparation:

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

Introduction

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

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

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

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

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

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

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

— innovation can present unanticipated challenges to experience,

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

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

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

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

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

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

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

— requirements and definitions: roman type;

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

— terms defined in Clause 3: bold.

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

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

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

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

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

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

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

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

Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

1 Scope

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

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

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

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

2 Normative references

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

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

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

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

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

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

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

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

ISO 5362, *Anaesthetic reservoir bags*

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

1) To be published.