TECHNICAL REPORT

ISO/TR 16142

Second edition
2006-01-15

Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

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

Reference number
ISO/TR 16142:2006(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 16142 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO/TR 16142:1999), which has been technically revised.

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. Standards supporting or referenced in regulatory requirements need to be developed and applied in such a way as to allow product innovation by industry while assuring safety and effectiveness.

Timely development and periodic revision make medical devices standards effective and efficient tools for supporting regulatory systems and for moving toward 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 may 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 should be based on the premise that:

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

— innovation may present unanticipated challenges to experience;

— rigid, mandatory, application of standards may 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;

— 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.

Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices

1 Scope

This Technical Report considers and identifies certain significant standards and guides that can be useful in the assessment of conformity of medical devices with recognized essential principles of safety and performance.

This Technical Report is intended for use by manufacturers, standardization bodies, regulatory bodies, and for conformity assessment purposes.

2 Terms and definitions

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

2.1
basic standard
standard which includes fundamental concepts, principles, and requirements with regard to general aspects applicable to a wide range of products, processes, or services

NOTE Basic standards are sometimes referred to as horizontal standards.

2.2
group standard
standard which includes safety and essential performance aspects applicable to several or a family of similar products, processes, or services dealt with by two or more technical committees or subcommittees, making reference, as far as possible, to basic standards

NOTE Group standards are sometimes referred to as semihorizontal standards.

2.3
product standard
standard which includes all necessary safety and essential performance aspects of a specific or a family of product(s), process(es), or service(s) within the scope of a single technical committee or subcommittee, making reference, as far as possible, to basic standards and group standards

NOTE Product standards are sometimes referred to as vertical standards.