AHWP/GHWP ANNUAL MEETING
30 NOV – 1 DEC 2021

ISO 16142-1:2016
ISO 16142-2:2017

MEDICAL DEVICES - RECOGNIZED ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE OF MEDICAL DEVICES -GENERAL ESSENTIAL PRINCIPLES AND ADDITIONAL SPECIFIC ESSENTIAL PRINCIPLES FOR MEDICAL DEVICES AND GUIDANCE ON THE SELECTION OF STANDARDS

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INTERNATIONAL STANDARD

ISO 16142-1

First edition
2016-03-01

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

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

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

Reference number
ISO 16142-1:2016(E)

INTERNATIONAL STANDARD

ISO 16142-2

First edition
2017-08

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

Reference number
ISO 16142-2:2017(E)

Developed by ISO/TC 210. Cancels and replaces ISO/TR 16142:2006, which has been technically revised with significant changes.

SCOPE:

- includes EPSP, identifies significant standards and guides that can be used in the assessment of conformity of a medical device to indicate a medical device is safe and performs as intended.
- 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).
- also identifies and describes the additional essential principles of safety and performance which need to be considered during the design and manufacturing process.

- ISO 16142-2 is intended to identify and describe the EPSP, 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.

CONTENTS

TYPES OF STANDARDS USEFUL TO DEMONSTRATE COMPLIANCE

Basic standard

- Broad and cross multiple sectors
- Examples are ISO 9001, ISO 14001, ISO 17000, IEC 61140.

Group standard

- Generally horizontal standards
- Examples are electrical safety standards, QMS, biological evaluation. Sterilisation, usability standards.

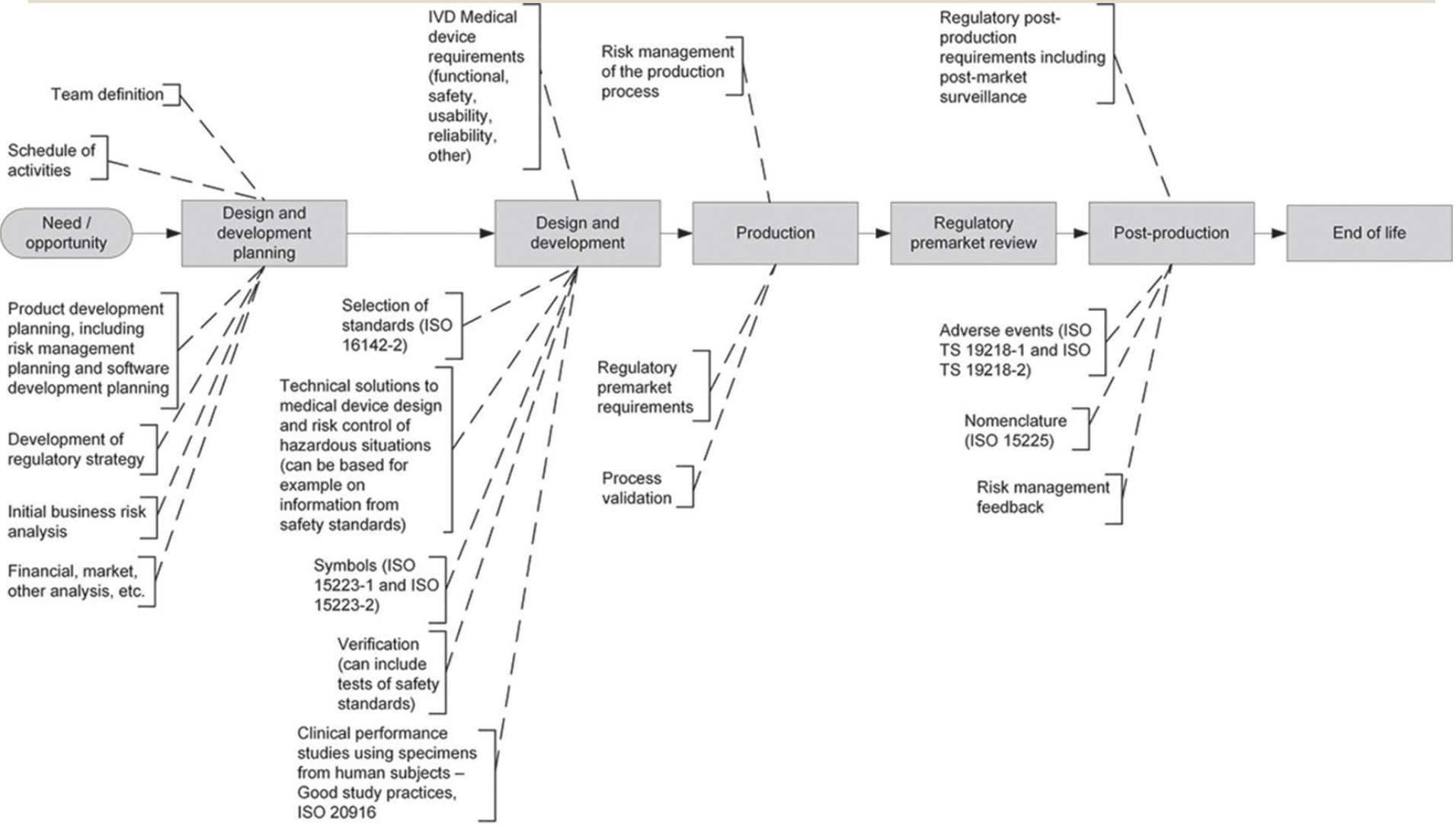
Product standard

- Vertical standards
- Product specific standards

Process standard

- Horizontal or vertical
- Examples: ISO 13485, ISO 14197, operation and maintenance standards

General approach to using standards



Assessing the conformity of a medical device

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

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

A manufacturer may not need to use an available standards and may create valid scientific evidence in lieu of using any standard to demonstrate conformance to the essential principles.

Essential principles and references to relevant standards and guides

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

TABLE B.1

No.	Essential principles of safety and performance of medical devices	References[a]
1	The medical device should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against benefits to the patient and are compatible with a high level of protection of health and safety.	ISO 14971 ISO 13485 ISO/TR 14969 ISO 14155 IEC 60601 (all parts) IEC/ISO 80601(all parts)
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. ….	ISO 14971 ISO 13485 ISO/TR 14969 ISO 10993-1 ISO 7405 IEC/TR 80002-1 IEC 60601 (all parts) IEC/ISO 80601(all parts)

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

Annexes In the Standard ISO 16142 - 1

Annex A (informative) Rational and guidance

- An understanding of the rationale for requirements is essential for their proper application.
- facilitate any revision of ISO 16142.

Annex B (normative) Table relating essential principle to standards

✓significant standards indicated for demonstrating compliance with certain features of the related EPSP.

✓The standards chosen for this Annex are not all inclusive.

✓primarily International Standards

✓regional or national standards are only used when International Standards do not exist.

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

Annex C (informative) Website listings of other standards suitable for the medical device sector and for assessment purpose.

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

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

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

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

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

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

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles.


thank
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