

**TR ISO/TR 24971 : 2020**  
**ISO/TR 24971:2020, IDT**  
(ICS 11.040.01)

**TECHNICAL REFERENCE**

**Medical devices — Guidance on the application  
of ISO 14971**



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*Edwards Lifesciences (Singapore) Pte Ltd*

*Sanmina Corporation Singapore*

*Singapore Manufacturing Federation (Medical Technology Industry Group)*

*Stendard*

*SystemED Pte Ltd*

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## **National Foreword**

This Technical Reference (TR) was prepared by the National Mirror Working Group on ISO/TC 210 set up by the Technical Committee on Quality Management Systems under the purview of BHSC.

This TR is identical with ISO/TR 24971:2020, Medical devices — Guidance on the application of ISO 14971, published by the International Organization for Standardization.

NOTE 1 – Reference to International Standards are replaced by applicable Singapore Standards/Technical References.

NOTE 2 – Where numerical values are expressed as decimals, the comma is read as a full point.

This TR is a provisional standard made available for application over a period of three years. The aim is to use the experience gained to update the TR so that it can be adopted as a Singapore Standard. Users of the TR are invited to provide feedback on its technical content, clarity and ease of use. Feedback can be submitted using the form provided in the TR. At the end of the three years, the TR will be reviewed, taking into account any feedback or other considerations, to further its development into a Singapore Standard if found suitable.

Attention is drawn to the possibility that some of the elements of this TR may be the subject of patent rights. Enterprise Singapore shall not be held responsible for identifying any or all of such patent rights.

### **NOTE**

- 1. Singapore Standards (SSs) and Technical References (TRs) are reviewed periodically to keep abreast of technical changes, technological developments and industry practices. The changes are documented through the issue of either amendments or revisions. Where SSs are deemed to be stable, i.e. no foreseeable changes in them, they will be classified as “Mature Standards”. Mature Standards will not be subject to further review, unless there are requests to review such standards.*
- 2. An SS or TR is voluntary in nature except when it is made mandatory by a regulatory authority. It can also be cited in contracts making its application a business necessity. Users are advised to assess and determine whether the SS or TR is suitable for their intended use or purpose. If required, they should refer to the relevant professionals or experts for advice on the use of the document. Enterprise Singapore and the Singapore Standards Council shall not be liable for any damages whether directly or indirectly suffered by anyone or any organisation as a result of the use of any SS or TR. Although care has been taken to draft this standard, users are also advised to ensure that they apply the information after due diligence.*
- 3. Compliance with a SS or TR does not exempt users from any legal obligations.*

## 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-and-policies](http://www.iso.org/directives-and-policies)).

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](http://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](http://www.iso.org/iso/foreword.html).

This document was prepared jointly by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*, and Subcommittee IEC/SC 62A, *Common aspects of electrical equipment used in medical practice*.

This second edition cancels and replaces the first edition, which has been technically revised. The main changes compared to the previous edition are as follows:

- The clauses of ISO/TR 24971:2013 and some informative annexes of ISO 14971:2007 are merged, restructured, technically revised, and supplemented with additional guidance.
- To facilitate the use of this document, the same structure and numbering of clauses and subclauses as in ISO 14971:2019 is employed. The informative annexes contain additional guidance on specific aspects of *risk management*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document provides guidance to assist *manufacturers* in the development, implementation and maintenance of a *risk management process* for *medical devices* that aims to meet the requirements of ISO 14971:2019, *Medical devices — Application of risk management to medical devices*. It provides guidance on the application of ISO 14971:2019 for a wide variety of *medical devices*. These *medical devices* include active, non-active, implantable, and non-implantable *medical devices*, software as *medical devices* and *in vitro diagnostic medical devices*.

The clauses and subclauses in this document have the same structure and numbering as the clauses and subclauses of ISO 14971:2019, to facilitate the use of this guidance in applying the requirements of the standard. Further division into subclauses is applied where considered useful. The informative annexes contain additional guidance on specific aspects of *risk management*. The guidance consists of the clauses of ISO/TR 24971:2013 and some of the informative annexes of ISO 14971:2007, which are merged, restructured, technically revised, and supplemented with additional guidance.

Annex H was prepared in cooperation with Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This document describes approaches that *manufacturers* can use to develop, implement and maintain a *risk management process* conforming to ISO 14971:2019. Alternative approaches can also satisfy the requirements of ISO 14971:2019.

When judging the applicability of the guidance in this document, one should consider the nature of the *medical device(s)* to which it will apply, how and by whom these *medical devices* are used, and the applicable regulatory requirements.

# Medical devices — Guidance on the application of ISO 14971

## 1 Scope

This document provides guidance on the development, implementation and maintenance of a *risk management* system for *medical devices* according to ISO 14971:2019.

The *risk management process* can be part of a quality management system, for example one that is based on ISO 13485:2016<sup>[24]</sup>, but this is not required by ISO 14971:2019. Some requirements in ISO 13485:2016 (Clause 7 on product realization and 8.2.1 on feedback during monitoring and measurement) are related to *risk management* and can be fulfilled by applying ISO 14971:2019. See also the ISO Handbook: *ISO 13485:2016 — Medical devices — A practical guide*<sup>[25]</sup>.

## 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 14971:2019, *Medical devices — Application of risk management to medical devices*