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Medical devices — Guidance on the application of ISO 14971

Dispositifs médicaux — Recommandations relatives à l'application de l'ISO 14971



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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-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).

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 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.

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.