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Medical devices — Examples of the application of the risk management process to cardiac valve replacement and repair systems

Dispositifs médicaux — Exemples d'application du processus de gestion des risques aux systèmes de remplacement et de réparation des valves cardiaques

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: 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.

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems.*

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.

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Introduction

Risk management is the underlying foundation of the product development process and should be considered throughout all phases of the product development cycle. This document provides guidance to assist manufacturers on the application of the risk management process, as described in ISO 13485 and ISO 14971, to cardiac valve replacement and repair systems. Figure 1 demonstrates the relationship between the risk and device standards as well as the applicable Technical Reports that support the risk management process.

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Medical devices — Examples of the application of the risk management process to cardiac valve replacement and repair systems

1 Scope

This document illustrates the implementation of the risk management process to the total product life cycle of cardiac valve replacement and repair systems. It provides specific examples of how risk management requirements and concepts can be applied to new or modified cardiac valve replacement and repair systems. The informative examples included herein are not exhaustive.

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 5840-2, *Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes*

ISO 5840-3, *Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques*

ISO 5910, *Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 5840-2, ISO 5840-3, ISO 5910 and ISO 14971 apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

NOTE The defined terms in ISO 5840-2, ISO 5840-3, ISO 5910 and ISO 14971 are derived as much as possible from ISO/IEC Guide 63, which was developed specifically for the medical device sector.

4 General risk management requirements

Decisions and actions, based on the information collected and analysed by application of this document, are described in other standards, such as ISO 13485, ISO 14971 and ISO/TR 24971, and are therefore not included in this document. The manufacturer may be required to perform other risk management activities to fulfil applicable regulatory requirements ISO/IEC Guide 63, for medical devices that are not discussed in this document. While regulatory requirements are not described here, this document can be helpful for manufacturers in fulfilling those regulatory requirements. This document uses the definition of risk management from ISO 13485 and ISO 14971.

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