INTERNATIONAL STANDARD

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# Instruments for use in association with non-active surgical implants — General requirements

*Instruments à utiliser en association avec les implants chirurgicaux non actifs — Exigences générales*

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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

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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).

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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This fourth edition cancels and replaces the third edition (ISO 16061:2015), which has been technically revised. The main changes compared to the previous edition are as follows:

— A requirement to include intended purpose has been added in the list of items to be included when establishing the intended performance of the instrument.

— The list of design attributes in Clause 5 has been reorganized and several new attributes have added to the list.

— The selection of materials to be used in the instrument has been based on a risk analysis and the clause now includes a list of the minimum factors to be considered in the risk analysis.

— The requirement for pre-clinical evaluation has been expanded and includes the requirement for testing and biological evaluation of the final instrument.

— A clinical evaluation of the instrument has been added as a requirement in all cases. However, if the pre-clinical evaluation demonstrates the safety and intended performance of the instrument in the conditions of intended use, the results of the pre-clinical evaluation will satisfy the requirement for the clinical evaluation.

— A new requirement for post-market surveillance has been added to Clause 7.

— The requirements in Clause 11 have been reorganized and clarified to reflect current practice and to reference ISO 17664:2017, Clause 6 for instructions for applicable processing step (i.e. cleaning, disinfection, drying, packaging, and sterilization) that need to be carried out by someone other than the manufacturer.

— Annex A has been simplified to provide more consistent guidance on selection of material using a risk-based approach. The stainless-steel grade material characteristic tables have been removed.

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 a method of addressing the fundamental principles outlined in ISO/TR 14283 as they apply to instruments to be used in association with non-active surgical implants. It also provides a method that can be used to demonstrate compliance with applicable regulatory requirements relevant to the general safety and performance of medical devices as they apply to instruments used in association with non-active surgical implants.

There are three levels of standards dealing with instruments to be used in association with non-active surgical implants. They are as follows, with level 1 being the highest.

— Level 1: general requirements for instruments to be used in association with non-active surgical implants.

— Level 2: particular requirements for families of instruments to be used in association with non-active surgical implants.

— Level 3: specific requirements for types of instruments to be used in association with non-active surgical implants.

Level 1 standards include this document which contains requirements that apply to all instruments to be used in association with non-active surgical implants, ISO 14630, which contains the requirement for non-active surgical implants and ISO 14708-1, which contains requirements for active implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards apply to a more restricted set or family of instruments, such as those designed for use with non-active surgical implants used in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards apply to specific types of instruments within a family of instruments used in association with non-active surgical implants, such as hip joints or arterial stents.

To address all requirements for a specific instrument, it is advisable that the standard of the lowest available level be consulted first.

Compliance with a level 3 standard is intended to imply compliance with the applicable level 2 standards, if available, and with the applicable level 1 standard.

NOTE The requirements in this document correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.

# Instruments for use in association with non-active surgical implants — General requirements

## 1 Scope

This document specifies the general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are supplied after refurbishment.

NOTE In this document, unless otherwise specified, the term "instrument" refers to an instrument for use in association with non-active surgical implants.

This document also applies to instruments which can be connected to power-driven systems, but it does not apply to the power-driven systems themselves.

With regard to safety, this document gives the requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the instrument manufacturer, hereafter referred to as the manufacturer.

This document is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.

## 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 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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