



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 14630:2022**  
**01-november-2022**

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**Neaktivni kirurški vsadki (implantati) - Splošne zahteve (ISO/DIS 14630:2022)**

Non-active surgical implants - General requirements (ISO/DIS 14630:2022)

Nichtaktive chirurgische Implantate - Allgemeine Anforderungen (ISO/DIS 14630:2022)

Implants chirurgicaux non actifs - Exigences générales (ISO/DIS 14630:2022)

**Ta slovenski standard je istoveten z: prEN ISO 14630**

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**ICS:**

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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**oSIST prEN ISO 14630:2022**

**en,fr,de**



# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 14630

ISO/TC 150

Secretariat: DIN

Voting begins on:  
2022-09-16Voting terminates on:  
2022-12-09

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## Non-active surgical implants — General requirements

*Implants chirurgicaux non actifs — Exigences générales*

ICS: 11.040.40

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Published in Switzerland

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## ISO/DIS 14630:2022(E)

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

ISO 14630 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

This fifth edition cancels and replaces the fourth edition (ISO 14630:2012), which has been technically revised. The main changes compared to the previous edition are as follows:

- revised the scope to clarify that this standard does not apply to implants incorporating viable animal or human tissue and implants intended to remain in place for less than 30 days;
- added definitions are added for demonstrably similar implant and reference implant to clarify when data for other implants can be used during pre-clinical and clinical evaluation of the implant under investigation;
- reorganized list of design attributes in [Clause 5](#) to put them in a more logical sequence;
- revised [Clause 6](#) on selection of material to use a risk analysis as the basis for selection of implant materials, and to list factors to be taken into account when performing the risk analysis;
- significantly expanded [Clause 7](#) on design evaluation to address pre-clinical evaluation, clinical evaluation and investigation, and post-market surveillance in more detail;
- expanded [Clause 8](#) on manufacturing to address cleanliness of the implant;
- revised [Clause 11](#) on information supplied by the manufacturer to include new subclause addressing patient record labels ([11.5](#)) and implant card ([11.6](#)).

## Introduction

This document provides a method of addressing the fundamental principles outlined in ISO/TR 14283 as they apply to 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 non-active surgical implants.

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves, they are as follows, with level 1 being the highest.

Level 1: General requirements for non-active surgical implants.

Level 2: Particular requirements for families of non-active surgical implants.

Level 3: Specific requirements for types of non-active surgical implants.

Level 1 standards include this document which contains requirements that apply to all non-active surgical implants, ISO 16061, which contains requirement for instruments associated with 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 (see References, [2], [12], [22], [26] and [41]) apply to a more restricted set or family of non-active surgical implants, such as those designed for use in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards (see References, [3], [13], [23] and [24]) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address the requirements for a specific implant, all related Level 1, 2 and 3 standards should all be applied.

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





# Non-active surgical implants — General requirements

## 1 Scope

This document specifies general requirements for non-active surgical implants, hereafter referred to as implants. This document is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses, the viable animal or human tissue components of implants containing viable animal or human tissue and implants intended to remain in place for less than 30 days after being implanted.

With regard to safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements.

Additional requirements applicable to specific implants or implant families are given or referred to in Level 2 and Level 3 standards.

NOTE 1 This document does not require that the manufacturer have a quality management system in place. However, many regulatory authorities require the application of a quality management system, such as that described in ISO 13485, to ensure that the implant achieves its intended performance and safety.

NOTE 2 In this document, when not otherwise specified, the term "implant" refers to each individual component of a system or a modular implant, provided separately or as a set of components, as well as to all ancillary implants or associated implants designed for improving the intended performance.

## 2 Normative references

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

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-17, *Biological evaluation of medical device — Part 17: Establishment of allowable limits for leachable substances*

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*

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ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

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

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

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*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 20857, *Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 80000-1, *Quantities and units — Part 1: General*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971 and the following terms and definitions apply.

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

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

#### 3.1 ancillary implant

an implantable device, not included as a component of an implant system, but without which the system cannot be surgically inserted

EXAMPLE Cement for cemented stem of a hip joint replacement, or screws for orthopaedic plates.

[SOURCE: ISO 16054:2019, 3.4]

### 3.2

#### **associated implant**

an implantable device, included as a component of a *modular implant* (3.14) or supplied separately, that is surgically inserted for the specific clinical condition to facilitate the use of the primary *implant* (3.15)

EXAMPLE An augmentation device used to stabilise the tibial tray of a knee joint replacement or the acetabular cup of a hip joint replacement; sleeves applied to the stem of a hip or knee joint prosthesis to fill canal defects and prevent rotation; a cement restrictor used in hip joint replacement to occlude the intramedullary canal.

[SOURCE: ISO 16054:2019, 3.5]

### 3.3

#### **$B_0$ hazard area**

space around the magnetic resonance equipment where the static magnetic field can cause harm

Note 1 to entry: The  $B_0$  hazard area is not identical to the special environment as defined in IEC 60601-1-2.

Note 2 to entry: The  $B_0$  hazard area is not identical to the *magnetic resonance environment* (3.11) as defined in IEC 62570.

[SOURCE: IEC 60601-2-33:2022, 201.3.202, modified — The abbreviation "MR" in the definition and Note 2 to entry replaced by "magnetic resonance".

### 3.4

#### **clinical evaluation**

assessment and analysis of clinical data pertaining to a medical device to verify the clinical safety and performance of the device when used as intended by the manufacturer

[SOURCE: GHTF/SG1/N68:2012, 4.0]

### 3.5

#### **clinical investigation**

systematic investigation or study in or on one or more human subjects, undertaken to assess the safety and/or performance of a medical device [SOURCE: GHTF/SG1/N70:2011, 4.0]

### 3.6

#### **coating**

layer of material covering or partially covering a surface of an *implant* (3.15)

### 3.7

#### **final implant**

*implant* (3.15) that has been subjected to all manufacturing processes including packaging, and if applicable, sterilization, and is ready to be marketed

Note 1 to entry: Derived from the definition of "final product" in ISO 10993-1:2018, 3.8 to reinforce that the implant to be evaluated is the final product referred to in ISO 10993-1.

### 3.8

#### **demonstrably similar implant**

legally-marketed *implant* (3.15) with the same intended use to the *implant* under evaluation for which similarity can be demonstrated in technical, biological and clinical characteristics based on proper scientific justification and to the extent that there would be no clinically significant difference in the safety and clinical performance of the *implants*

Note 1 to entry: Manufacturers shall have sufficient levels of access to the data relating to implants with which they are claiming similarity in order to justify their claims of similarity.

Note 2 to entry: In a demonstrably similar implant, most of the performance parameters under consideration are similar to the implant whereas in a reference implant as few as one performance parameter may be considered.

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Note 3 to entry: Some regulatory authorities require that a demonstrably similar implant is one that is legally marketed in their own country or jurisdiction. This fact can be taken into account when selecting a demonstrably similar implant for the purposes of this document.

Note 4 to entry: For a demonstrably similar implant, there shall be evidence of successful clinical use in sufficient numbers; for a sufficient period of time; and, at a minimum, without known or reasonably known evidence of design or performance-related recalls.

Note 5 to entry: The manufacturer is responsible for identifying the demonstrably similar implant in accordance with the regulatory requirements in the jurisdictions where the implant under evaluation is to be marketed.

### 3.9 implantable state

condition of an *implant* (3.15) prepared for implantation into a human subject

### 3.10 leakage

unintended movement of fluid, including body fluids, into or out of an *implant* (3.15)

Note 1 to entry: An unintended diffusion phenomenon is an example of leakage for the purposes of this document.

### 3.11 magnetic resonance environment MR environment

three-dimensional volume surrounding the magnetic resonance magnet that contains both the special environment (Faraday shielded volume) and the  $B_0$  hazard area (3.3). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the magnetic resonance equipment and accessories, and for which access control is part of the risk mitigation.

Note 1 to entry: The entrance to the MR environment is controlled by the responsible organization. The area to which entry is controlled is sometimes referred to as the magnetic resonance controlled access area.

[SOURCE: IEC 60601-2-33:2022, 201.3.224, modified — The abbreviation "MR" in the definition and the notes to entry replaced by "magnetic resonance".]

### 3.12 magnetic resonance imaging MRI

imaging technique that uses a static magnetic field, time-varying gradient magnetic fields, and radio frequency fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ASTM F2182-19e2, 3.1.6]

### 3.13 manufacturer

natural or legal person with responsibility for design and/or manufacture of an *implant* (3.15) with the intention of making the *implant* available for use, under his name, whether or not such an *implant* is designed and/or manufactured by that person himself or on his behalf by another person(s)

Note 1 to entry: This natural or legal person has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the *implant* in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.

Note 2 to entry: The manufacturer's responsibilities are described in other Global Harmonization Task Force (GHTF) guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.

Note 3 to entry: "Design and/or manufacture" can include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of an *implant*; or putting a collection of devices, and possibly other products, together for a medical purpose.