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STN	**Neaktívne chirurgické implantáty Všeobecné požiadavky (ISO 14630: 2024)**	**STN EN ISO 14630 85 2905**

Non-active surgical implants - General requirements (ISO 14630:2024)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/25

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NORME EUROPÉENNE
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EN ISO 14630

December 2024

ICS 11.040.40 Supersedes EN ISO 14630:2012

English Version

Non-active surgical implants - General requirements (ISO 14630:2024)

Implants chirurgicaux non actifs - Exigences générales (ISO 14630:2024)

Nichtaktive chirurgische Implantate - Allgemeine Anforderungen (ISO 14630:2024)

This European Standard was approved by CEN on 17 July 2024.

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European foreword

This document (EN ISO 14630:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2025, and conflicting national standards shall be withdrawn at the latest by June 2025.

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

This document supersedes EN ISO 14630:2012.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 14630:2024 has been approved by CEN as EN ISO 14630:2024 without any modification.

Annex ZA
(informative)

Relationship between this European Standard the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences are indicated in the Annex ZA. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this document can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region the standard can only support European regulatory requirements to the extent of the scope of the European Regulation for medical devices ((EU) 2017/745).

For application of this European standard under Regulation (EU) 2017/745,

1. it is recognized that the normatively referenced ISO 10993-1 includes a dated reference to ISO 14971:2007 which is outdated and for application of this European standard under Regulation (EU) 2017/745 the most recent European version EN ISO 14971:2019 + A11:2021 shall be used;

2. it is recognized that the limits for residuals of ethylene oxide referenced in 9.4 and specified in the normatively referenced EN ISO 10993-7:2008 + AC 2009 + A1 2022 are not designed for patients with weight lower than 70 kg and are in particular not appropriate for neonates and other patients with a weight substantially below 70 kg;

3. it is recognized that the normatively referenced ISO 20857 refers to “applicable clauses of ISO 13485” and that for application of this European standard under Regulation (EU) 2017/745 the most recent European version EN ISO 13485:2016 + AC:2018 + A11:2021 shall be used.

4. it is recognized that the normatively referenced ISO 22442-1 states in its introduction that it can only be used in combination with ISO 14971 and is not a “stand-alone” standard and it is also recognized that for application of this European standard under Regulation (EU) 2017/745 the most recent European version EN ISO 14971:2019 + A11:2021 shall be used;

5. it is recognized that this European standard does not cover any of the legal requirements of Regulation (EU) 722/2012 which are applicable to devices or system or process requirements falling under its scope.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible' or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Differences in definitions of the terms set out in Regulation (EU) 2017/745

Definition in Regulation (EU) 2017/745, Article 2	**Definition in EN ISO 14630**	**Explanation**
44 'clinical evaluation means a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance including clinical benefits of the device when used as intended by the manufacture'	**3.4 clinical evaluation:** set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the device when used as intended by the manufacturer	Since EN ISO 14630 is based on an international standard, the definition in the standard is taken from IMDRF MDCE WG/N56FINAL:2019, 4.0. While the exact wording differs, the intent of the definitions seems to be mostly identical. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.
45 'clinical investigation means any systematic investigation involving one or more human subjects undertaken to assess the safety or performance of a device'	**3.5 clinical investigation** systematic investigation or study in or on one or more human subjects, undertaken to assess the safety, clinical performance and/or effectiveness of a medical device	Since EN ISO 14630 is based on an international standard, the definition in the standard is taken from IMDRF MDCE WG/N56FINAL:2019, 4.0. While the exact wording differs, the intent of the definitions seems to be mostly identical. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.
30 'manufacturer means a natural or legal person who manufacturers or fully refurbishes a device or has a device designed, manufactured or fully refurbished and	**3.12 manufacturer:** natural or legal person with responsibility for design and/or manufacture of an *implant* (3.14) with the intention of making the *implant* available for use, under his name, whether or	Since EN ISO 14630 is based on an international standard, the definition in the standard is taken from ISO 14971:2019, 3.9 and was only slightly modified by replacing "Medical device" by "*implant*". For the purpose of using this standard in support of the requirements set out in

markets that device under its name or trademark'	not such an *implant* is designed and/or manufactured by that person himself or on his behalf by another person(s)	Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
23.1 (a)	11.3	23.1 (a) is covered with respect to legibility of the label by 11.3 (Label) which requires that the information on the label shall be legible under illumination of 215 lux using normal vision at a distance of 1 m.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Reference in Clause 2	International Standard Edition	Title	Corresponding European Standard Edition
ISO 10993-1	ISO 10993-1:2018	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
ISO 10993-7	ISO 10993-7:2008 + Cor 1:2009 + Amd 1: 2019	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	EN ISO 10993-7:2008 + AC:2009 + A1:2022
ISO 10993-17	ISO 10993-17:2023	Biological evaluation of medical device — Part 17: Toxicological risk assessment of medical device constituents	EN ISO 10993-17:2023
ISO 11135	ISO 11135:2014 + Amd 1:2018	Sterilization of health care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 11135:2014 + A1:2019
ISO 11137-1	ISO 11137-1:2006 + Amd 1:2013 + Amd 2:2018	Sterilization of health care products — Radiation — Part 1: Requirements for development,	EN ISO 11137-1:2015 + A2:2019

		validation and routine control of a sterilization process for medical devices	
ISO 11137-2	ISO 11137-2:2013 + Amd 1:2022	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	EN ISO 11137-2:2015 + A1:2023
ISO 11137-3	ISO 11137-3:2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control	EN ISO 11137-3:2017
ISO 11607-1	ISO 11607-1:2019 + Amd 1:2023	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020 + A1:2023
ISO 11607-2	ISO 11607-2:2019 + Amd 1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	EN ISO 11607-2:2020 + A1:2023
ISO 13408-1	ISO 13408-1:2023	Aseptic processing of health care products — Part 1: General requirements	EN ISO 13408-1:2024
ISO 14155	ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice	EN ISO 14155:2020
ISO 14160	ISO 14160:2020	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	EN ISO 14160:2021
ISO 14937	ISO 14937:2009	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	EN ISO 14937:2009
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 + A11:2021
ISO 17664-1	ISO 17664-1:2021	Processing of health care products — Information to be provided by	EN ISO 17664-1:2021

		the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	
ISO 17665	ISO 17665:2024	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 17665:2024
ISO 20857	ISO 20857:2010	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	EN ISO 20857:2013
ISO 22442-1	ISO 22442-1:2020	Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management	EN ISO 22442-1:2020
ISO 22442-2	ISO 22442-2:2020	Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling	EN ISO 22442-2:2020
ISO 22442-3	ISO 22442-3:2007	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	EN ISO 22442-3:2007
ISO 25424	ISO 25424:2018 + Amd 1:2022	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	EN ISO 25424:2019 + A1:2022
ISO 80000-1	ISO 80000-1:2022	Quantities and units — Part 1: General	EN ISO 80000-1:2022

The documents listed in the Column 1 of table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of table ZA.2.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 14630

Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

Fifth edition
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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.

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 document 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).

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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 fifth edition cancels and replaces the fourth edition (ISO 14630:2012), which has been technically revised.

The main changes are as follows:

— the scope has been revised to clarify that this document does not apply to implants utilizing viable animal or human tissue;

— definitions have been added for clinical evaluation and clinical investigation based on the International Medical Device Regulators Forum (IMDRF) guidance on clinical evaluation;

— definitions have been 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;

— indications, contraindications and target patient population have been added in Clause 4 to the list of factors to consider when establishing the intended performance of an implant;

— reorganized list of design attributes in Clause 5 to put then 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;

— Clause 7 has been significantly expanded on design evaluation to address pre-clinical evaluation, clinical evaluation and investigation, and post-market surveillance in more detail;

— Clause 8 has been expanded on manufacturing to address cleanliness of the implant;

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— subclause 9.1 has been revised to list the methods of sterilizing the implant in a tabular form rather than as running text;

— a new subclause 10.3 has been added to address the determination of the use by date;

— Clause 11 has been revised on information supplied by the manufacturer to include new subclauses addressing patient record labels (11.5) and implant card (11.6);

— the subclause on restrictions on combinations (formerly 11.4) has been deleted because the safety of combinations is addressed in Clause 5 l).

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

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, and ISO 16061, which contains requirement for instruments associated with non-active surgical implants. They also anticipate that there are additional requirements in the Level 2 and Level 3 standards.

Level 2 standards (see References [2], [12], [23], [27] and [42]) 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], [24] and [25]) 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 be applied.

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International Standard **ISO 14630:2024(en)**

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 and implants utilizing viable animal or human tissue.

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 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 devices — Part 17: Toxicological risk assessment of medical device constituents*

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, *Sterilization of health care products — Moist heat — 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*

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