ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA November 2025

STN	**Neaktívne chirurgické implantáty Prsné implantáty Osobitné požiadavky (ISO 14607: 2024)**	**STN EN ISO 14607** 85 2943

Non-active surgical implants - Mammary implants - Specific requirements (ISO 14607:2024)

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. 10/25

Obsahuje: EN ISO 14607:2025, ISO 14607:2024

Oznámením tejto normy sa ruší
STN EN ISO 14607 (85 2943) z novembra 2018

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14607

August 2025

ICS 11.040.40 Supersedes EN ISO 14607:2018

English Version

Non-active surgical implants - Mammary implants - Specific requirements (ISO 14607:2024)

Implants chirurgicaux non actifs - Implants mammaires - Exigences particulières (ISO 14607:2024)

Nichtaktive chirurgische Implantate - Mammaimplantate - Besondere Anforderungen (ISO 14607:2024)

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 14607:2025) 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of an identical text or by endorsement, at the latest by February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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 14607:2018.

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 14607:2024 has been approved by CEN as EN ISO 14607:2025 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 harmonized standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences are indicated in the Annex Z. 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).

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.

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) / subclause(s) of this EN	Remarks / Notes
10.1(a)	6.3, 6.4.1	10.1(a) is covered with respect to the choice of silicone gel materials based on their combined residual oligomers, regarding toxicity by 6.3. 10.1(a) is covered with respect to the choice of raw materials based on unintentional trace elements in them, regarding toxicity by 6.4.1.
10.1(b)	7.2.1, 7.2.5	10.1(b) is covered with respect to the pre-clinical biological evaluation of compatibility of the breast implants with biological tissues by 7.2.1 and 7.2.5. However, some parts of 7.2.1 and 7.2.5 contain recommendations rather than requirements, which limits their usefulness for the coverage of 10.1(b).
10.1(f)	7.2.2.1, Annex B 7.2.2.2, Annex C 7.2.3.3.2, Annex E	10.1(f) is covered with respect to shell integrity by 7.2.2.1 and Annex B. 10.1(f) is covered with respect to implant resistance by 7.2.2.2 and Annex C. 10.1(f) is covered with respect to silicone gel cohesion by 7.2.3.3.2 and Annex E.
10.1(g)	7.2.3.7, Annex G	10.1(g) is covered by 7.2.3.7 and Annex G.
10.1(h)	Annex A Annex B Annex C Annex E Annex F Annex G	10.1(h) is covered with respect to the confirmation that the raw silicone gel meets specifications regarding combined residual oligomers by Annex A. 10.1(h) is covered with respect to the confirmation that implant meets specifications regarding shell integrity by Annex B. 10.1(h) is covered with respect to the confirmation that the implant meets specifications regarding implant fatigue, impact resistance, and endurance load level by Annex C. 10.1(h) is covered with respect to the confirmation that the silicone gel meets specifications regarding silicone gel cohesion by Annex E. 10.1(h) is covered with respect to the confirmation that the silicone gel meets specifications regarding silicone gel penetration by Annex F. 10.1(h) is covered with respect to the confirmation that the silicone gel meets specifications regarding

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General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
		surface classification by Annex G.
23.1(g)	Annex I e), Annex I g)	23.1(g) is covered with respect to information and warnings supplied by the manufacturer to patients regarding residual risks, potential harm, and adverse effects by Annex I e) and Annex I g).

Table ZA.2 — Normative references from clause 2 of this document and their corresponding European publications

Reference in Clause 2	International Standard Edition	Title	Corresponding European Standard Edition
ISO 34-1:2022	ISO 34-1:2022	Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces	For applicable standard edition see Column 2
ISO 37:2017	ISO 37:2017	Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties	For applicable standard edition see Column 2
ISO 48-4	ISO 48-4:2018	Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)	For applicable standard edition see Column 2
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 10993-5	ISO 10993-5:2009	Biological evaluation of medical devices — Part 5: Tests for *in vitro* cytotoxicity	EN ISO 10993-5:2009
ISO 10993-6	ISO 10993-6:2016	Biological evaluation of medical devices — Part 6: Tests for local effects after implantation	EN ISO 10993-6:2016
ISO 10993-18	ISO 10993-18:2020 and ISO 10993-18:2020/Amd 1:2022	Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials	EN ISO 10993-18:2020+A1:2023

Reference in Clause 2	International Standard Edition	Title	Corresponding European Standard Edition
		within a risk management process	
ISO/TS 10993-20	ISO/TS 10993-20: 2006	Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices	For applicable standard edition see Column 2
ISO 11607-1	ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	EN ISO 11607-1:2020
ISO 14155	ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice	EN ISO 14155:2020
ISO 14630:2024	ISO 14630:2024	Non-active surgical implants — General requirements	EN ISO 14630:2024
ISO 14971	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 + A11:2021
ISO 20417	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	EN ISO 20417:2021
ISO 21920-2	ISO 21920-2:2021	Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters	EN ISO 21920-2:2022
ASTM D412	None	Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension	None
ASTM D624-00 (2020)	None	Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications	None
ASTM D792	None	Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement	None

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Reference in Clause 2	International Standard Edition	Title	Corresponding European Standard Edition
ASTM D2240	None	Standard Test Method for Rubber Property — Durometer Hardness	None

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 14607

Non-active surgical implants — Mammary implants — Specific requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 14607:2018), which has been technically revised.

The main changes are as follows:

— trace elements subclause (6.4) has been revised;

— language regarding biological evaluation and risk management has been revised and expanded in the general part of the pre-clinical evaluation subclause (7.2.1);

— contamination subclause has been renamed to particulate contamination (7.2.3.8) and completely revised;

— requirements regarding implantation studies have been added (7.2.5);

— clinical evaluation requirements have been expanded (7.3);

— surface category has been added to the label requirements (11.3);

— Annex C “Mechanical tests on a mammary implant in its implantable state” has been expanded and revised;

— the fatigue resistance testing method (Clauses C.1 and C.3) has been revised and expanded;

— Annex F “Test for silicone gel penetration (silicone filling materials only)” has been re-structured and the language has been clarified;

— Annex G “Assessment of silicone diffusion from mammary implants using an in vitro method” has been deleted as the test method given in the annex did not accomplish its purpose;

— Annex H “Test for surface characteristics” has been re-numbered as Annex G and has been renamed “Surface classification”, its status has been changed to normative, it has completely revised and an expanded surface classification has been added;

— Annex J “Tests for surface particulate contamination” has been newly added;

— the language of test report subclauses in all annexes has been harmonized as much as possible.

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

There are three levels of International Standards dealing with non-active surgical implants. These 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.

This document is a level 3 standard and contains specific requirements for mammary implants.

The level 1 standard, ISO 14630, contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards.

To address all requirements, the lowest available level is the level to start with.

International Standard **ISO 14607:2024(en)**

Non-active surgical implants — Mammary implants — Specific requirements

1 Scope

This document specifies specific requirements for mammary implants. With regard to safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, packaging, sterilization and information supplied by the manufacturer.

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 34-1:2022, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 37:2024, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 48-4, *Rubber, vulcanized or thermoplastic — Determination of hardness — Part 4: Indentation hardness by durometer method (Shore hardness)*

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

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

ISO 10993-6, *Biological evaluation of medical devices — Part 6: Tests for local effects after implantation*

ISO 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process*

ISO/TS 10993-20, *Biological evaluation of medical devices — Part 20: Principles and methods for immunotoxicology testing of medical devices*

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

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

ISO 14630:2024, *Non-active surgical implants — General requirements*

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

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

ISO 21920-2, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 2: Terms, definitions and surface texture parameters*

ASTM D412, *Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension*

ASTM D624-00 (2020), *Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications*

ASTM D792, *Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement*

ASTM D2240, *Standard Test Method for Rubber Property — Durometer Hardness*