SLOVENSKI STANDARD
SIST EN ISO 14607:2025

01-oktober-2025

Nadomešča:
SIST EN ISO 14607:2018

Neaktivni kirurški vsadki (implantati) - Prsni vsadki - Posebne zahteve (ISO 14607:2024)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 14607:2025**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 14607:2025 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 14607

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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

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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