



SLOVENSKI STANDARD
oSIST prEN ISO 14607:2023

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Neaktivni kirurški vsadki (implantati) - Prsni vsadki - Posebne zahteve (ISO/DIS 14607:2023)

Non-active surgical implants - Mammary implants - Particular requirements (ISO/DIS 14607:2023)

Nichtaktive chirurgische Implantate - Mammaimplantate - Besondere Anforderungen (ISO/DIS 14607:2023)

Implants chirurgicaux non actifs - Implants mammaires - Exigences particulières (ISO/DIS 14607:2023)

Ta slovenski standard je istoveten z: prEN ISO 14607

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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Non-active surgical implants — Mammary implants — Specific requirements

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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 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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*,

This fourth edition cancels and replaces the third edition (ISO 14607:2018), which has been technically revised.

The main changes compared to the previous edition are as follows:

- trace elements [subclause \(6.4\)](#) was revised;
- language regarding biological evaluation and risk management was revised and expanded in the general part of the pre-clinical evaluation [subclause \(7.2.1\)](#);
- contamination subclause was re-named to particulate contamination ([7.2.3.8](#)) and completely revised;
- requirements regarding implantation studies were added ([7.2.5](#));
- clinical evaluation requirements were expanded ([7.3](#));
- surface category was added to the label requirements ([11.3](#));
- [Annex C](#) “Mechanical tests on a mammary implant in its implantable state” was expanded and revised;
- the fatigue resistance testing method (Annex [C.1](#) and [C.3](#)) was revised and expanded;
- [Annex F](#) “Test for silicone gel penetration (silicone filling materials only)” was re-structured and the language clarified;
- [Annex G](#) “Assessment of silicone diffusion from mammary implants using an in vitro method” because it was agreed that the test method given in the Annex did not accomplish its purpose;
- [Annex H](#) “Test for surface characteristics” was re-numbered to [Annex G](#) and changed to normative, completely revised and an expanded surface classification was added;

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- [Annex J](#) “Tests for surface particulate contamination” was newly added;
- the language of test report subclauses in all Annexes was harmonized as much as possible.
- the document was editorially revised.

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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.

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Non-active surgical implants — Mammary implants — Specific requirements

1 Scope

This document specifies particular 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 37:2017, *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 14630:2023, *Non-active surgical implants — General requirements*

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

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*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10993-1, ISO 14155 and ISO 14630 and the following 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 anterior projection

maximum height of the implant when placed with its base on a flat horizontal surface

Note 1 to entry: For inflatable and adjustable implants, this applies to the implant's nominal volume.

3.2 base dimension

length of the major axis and the length of the minor axis when the implant is placed with its base on a flat horizontal surface

Note 1 to entry: For inflatable and adjustable implants, this applies to the implant's nominal volume.

3.3 cure

process of crosslinking silicone polymers

3.4 diffusion

movement of material in and/or out of an implant through an intact shell

3.5 filling volume

volume of the material contained within the shell or volume of the solution necessary to fill an inflatable or adjustable *mammary implant* (3.8)

3.6 implant volume

volume of the shell and filler material together

3.7 injection site

component designed to be penetrated by a needle to alter the volume of the implant

3.8 mammary implant

implant with a *shell* (3.13) which has been filled by the *manufacturer* (3.9) or is designed to be filled by the surgeon, and is intended to add or replace volume of the breast

3.9 manufacturer

natural or legal person who manufactures or fully refurbishes a medical device, or has a device designed, manufactured, or fully refurbished, and markets that medical device under its name or trademark

[SOURCE: ISO 10993-18:2020, 3.2]

3.10**orientation means**

mark in or on the implant to assist the surgeon in positioning the implant

3.11**particle free water**

purified water that has been passed through a suitable filter of 0,22 µm pore size

[SOURCE: USP 43-NF 38 – Reagent Specifications]

3.12**particulate contamination**

extraneous particles that are unintentionally present on the surface of an implant

Note 1 to entry: Particulate contamination can come from many sources during the manufacturing process.

3.13**shell**

envelope of the *mammary implant* (3.8)

3.14**seam**

seal junction of implant materials fused or adhered together

3.15**silicone elastomer**

synthetic rubber obtained by the crosslinking of silica reinforced *silicone polymer* (3.17) chains essentially made of repeat diorganosiloxane units

3.16**silicone gel**

semisolid material consisting of crosslinked *silicone polymer* (3.17) and liquid *silicone polymer* (3.17) (silicone oil or polydimethylsiloxane (PDMS))

3.17**silicone polymer**

polymer chains essentially made of repeat organosiloxane units

Note 1 to entry: The silicone polymers can be presented in many levels of viscosity.

3.18**supplier**

company which manufactures and/or supplies the raw materials and components used for the production of mammary implants

3.19**tensile set**

tensile elongation remaining after a specimen has been stretched and allowed to relax in a controlled manner

3.20**valve**

shell (3.13) component allowing inflation of mammary implant with variable volumes of liquids when needed and providing a tight closure the rest of the time

4 Intended performance

The requirements of ISO 14630:202X, Clause 4, shall apply.

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5 Design attributes

The requirements of ISO 14630:202X, Clause 5, shall apply.

6 Materials

6.1 General

The requirements of ISO 14630:202X, Clause 6, shall apply.

Materials shall be manufactured and tested under an appropriate quality management system.

NOTE 1 ISO 13485 is an example of quality management standard, which could be appropriate depending on local or regional regulation.

The information stated within [Clause 6](#) shall be available from the manufacturer.

NOTE 2 This information can typically be obtained from the raw material supplier.

When materials other than silicone are used, the manufacturer shall establish suitable test methods and acceptance criteria to demonstrate the appropriate performance and safety of the implant.

6.2 Cytotoxicity

Each raw material lot shall be tested for cytotoxicity in accordance with ISO 10993-5. The test specimens shall be representative of the materials used in the manufacture of mammary implants and should be cured as appropriate in advance of testing. No cytotoxic effects, as defined in ISO 10993-5, shall occur.

6.3 Silicone gel residual low molecular weight oligomers

The combined residual oligomers, octamethylcyclotetrasiloxane (D4), decamethylcyclopentasiloxane (D5) and dodecamethylcyclohexasiloxane (D6), in uncured or cured silicone gel shall be tested in accordance with [Annex A](#). These shall be reported in mg/kg or ppm and the total concentration of D4, D5, D6 combined shall not exceed 150 mg/kg or 150 ppm (see also [A.9](#)).

6.4 Trace elements

6.4.1 General

The presence of trace elements in raw materials can have two distinct sources:

- The first one is unintentional: they generally are residual substances entrapped into the ingredients used to formulate the raw materials. As such, they can be considered as impurities and shall not be present above a defined content limit, as reported in [Table 1](#):

Table 1 — Unintentional trace elements impurities limit content

Element	Content limit per element (mg/kg)
As, Ba, Cd, Co, Cr, Cu, Hg, Mo, Ni, Pb, Pt, Sb, Se, Sn, V	≤10

- The second one is intentional, that is, they are part of the product formulation. Typical examples of such intentional elements are some metals, like Platinum (Pt), used under the form of a complex to catalyze the curing reaction of some silicones. In this case, they shall not be considered as impurities and shall rather be taken into account in the larger context of the toxicological evaluation of the implant.

6.4.2 Intentionally added trace elements

If one of these trace elements is part of the formulation component, it is not considered an impurity.

Two trace elements which are commonly added are Platinum (Pt) and Tin (Sn).

If the cross-linking reaction of some silicones used for breast implants is catalysed by a platinum complex, the concentration of platinum in the final silicone component after the cross-linking reaction should not exceed 30 mg/kg.

If the cross-linking reaction of some silicones used for breast implants is catalysed by a tin complex, the concentration of tin in the final silicone component after the cross-linking reaction should not exceed 450 mg/kg.

6.5 Physico-mechanical properties and characterization

The following mechanical characteristics of the shell material (e. g. silicone elastomers, after cure) shall be available for every raw material lot:

- elongation at break, in percentage (%), according to ISO 37 or ASTM D412
- tensile strength at break, in megapascals (MPa), according to ISO 37 or ASTM D412
- modulus at 100 % elongation, in megapascals (MPa), according to ISO 37 or ASTM D412
- hardness, according to ASTM D2240 or ISO 48-4
- relative density, or specific gravity, according to ASTM D792
- tear strength, in kilonewtons per meter (kN/m), according to ISO 34-1:2022, Method C, or ASTM D624-00 (2020), Die B.

Every raw material lot of silicone gel shall be tested in accordance with [Annex F](#) and shall comply with the specifications of the raw material manufacturer.

6.6 Documentation of materials

For each type of material the manufacturer shall have available a certificate of analysis including at least the following information:

- a) supplier's name, address and contact details;
- b) material reference;
- c) test result including test methods applied for [6.2](#);
- d) for silicone gels test results including sample preparation (e. g. cure condition) for [6.3](#);
- e) test results including the test methods and sample preparation applied for [6.4](#);
- f) test results including defined acceptance criteria, test methods applied and sample preparation (e. g. cure condition) for [6.5](#).

7 Design evaluation

7.1 General

The requirements of ISO 14630:202X, 7.1, shall apply.

An appropriate risk management process in accordance with ISO 14971 shall be established for all stages in the life cycle of the implant.