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Non-active surgical implants — Mammary implants — Specific requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

~~Fourth edition~~

~~Date: 2023-11-01~~

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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 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 \(6.4\)](#) ~~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 \(7.2.1\)](#) ~~subclause (7.2.1)~~;
- ~~contamination~~ subclause was re-named to particulate contamination ([7.2.3.8](#) ~~(7.2.3.9)~~) and completely revised;
- ~~requirements regarding implantation studies~~ were added ([7.2.5](#) ~~(7.2.5)~~);
- ~~clinical evaluation requirements~~ were expanded ([7.3](#) ~~(7.3)~~);
- ~~surface category~~ was added to the label requirements ([11.3](#) ~~(11.3)~~);

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- ~~Annex C~~ **Annex C** “Mechanical tests on a mammary implant in its implantable state” was expanded and revised;
- ~~the~~ the fatigue resistance testing method (~~Annex C.1~~ (Clauses C.1 and C.3.C.3)) was revised and expanded;
- ~~Annex F~~ **Annex F** “Test for silicone gel penetration (silicone filling materials only)” was re-structured and the language clarified;
- ~~Annex G~~ **Annex G** “Assessment of silicone diffusion from mammary implants using an in vitro method” was deleted because it was agreed that the test method given in the Annex did not accomplish its purpose;
- ~~Annex H~~ **Annex H** “Test for surface characteristics” was re-numbered to ~~Annex G~~ **Annex G**, re-named to “Surface classification” and changed to normative, completely revised and an expanded surface classification was added;
- ~~Annex I~~ **Annex I** “Tests for surface particulate contamination” was newly added;
- ~~the~~ the language of test report subclauses in all Annexes was 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.

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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~~**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:~~2017~~**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* [4b6d-bd67-791a276dca19/iso-fdis-14607](https://standards.iteh.ai/4b6d-bd67-791a276dca19/iso-fdis-14607)

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~~**2024**, *Non-active surgical implants — General requirements*

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

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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*

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 terminology databases for use in standardization at the following addresses:

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

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~~cross-linking silicone polymers (3.17)

3.4

diffusion

movement of material in and/or out of an implant through an intact shell (3.13)

3.5

filling volume

volume of the material contained within the shell (3.13) or volume of the solution necessary to fill an inflatable or adjustable mammary implant (3.8~~(3.9)~~)

3.6

implant volume

volume of the shell (3.13) 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(3.13)) which has been filled by the *manufacturer* (3.9(3.9)) or is designed to be filled by the surgeon, and is intended to add or replace the 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, 3.23]

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^[4]]

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(3.8))

3.14

seam

seal junction of implant materials fused or adhered together

3.15

silicone elastomer

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

3.16

silicone gel

~~semisolid~~semi-solid material consisting of ~~crosslinked~~cross-linked *silicone polymer* (3.17(3.17)) and liquid silicone polymer ~~(silicone oil or polydimethylsiloxane (PDMS))~~

**3.17
silicone polymer**

polymer chains essentially made of ~~repeat~~repeated 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* (3.8)

**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(3.13)) component allowing inflation of *mammary implant* (3.8) with variable volumes of liquids when needed and providing a tight closure the rest of the time

4 Intended performance

The requirements of ISO 14630:2023/2024, Clause 4, shall apply.

5 Design attributes

The requirements of ISO 14630:2023/2024, Clause 5, shall apply.

6 Materials

6.1 General

The requirements of ISO 14630:2023/2024, Clause 6, shall apply. [ISO/FDIS 14607](https://standards.iteh.ai/catalog/standards/iso/998d52ac-41e8-4b6d-bd67-791a276dca19/iso-fdis-14607)

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

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

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