SLOVENSKI STANDARD
oSIST prEN ISO 14607:2017

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Neaktivni kirurški vsadki (implantati) - Prsni vsadki - Posebne zahteve (ISO/DIS 14607:2017)

Non-active surgical implants - Mammary implants - Particular requirements (ISO/DIS 14607:2017)

Nichtaktive chirurgische Implantate - Mammaimplantate - Besondere Anforderungen (ISO/DIS 14607:2017)

Implants chirurgicaux non actifs - Implants mammaires - Exigences particulières (ISO/DIS 14607:2017)

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Non-active surgical implants — Mammary implants — Particular 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 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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.

The committee responsible for this document is ISO/TC 150, Implants for surgery.

This third edition cancels and replaces the second edition (ISO 14607:2007), which has been technically revised.

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 is a level 2 standard and contains particular requirements for a family of 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, it is necessary to start with a standard of the lowest available level.

Non-active surgical implants — Mammary implants — Particular requirements

1 Scope

This International Standard specifies particular requirements for mammary implants

With regard to safety, this International Standard 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, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

ISO 37:2011, *Rubber, vulcanized or thermoplastic — Determination of tensile stress-strain properties*

ISO 4287, *Geometrical Product Specification (GPS) — Surface Textured : Profile method – Terms, definitions and surface texture parameters*

ISO 7619-1, *Rubber, vulcanized or thermoplastic — Determination of indentation hardness — Part 1: 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 10993-18, *Biological evaluation of medical devices — Part 18: Chemical characterization of materials*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

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

ISO 14630:2012, *Non-active surgical implants — General requirements*

NOTE The Bibliography gives informative references to other useful standards.

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 http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
anterior projection
maximum height of the implant when placed with its base on a flat horizontal surface at its nominal volume

3.2
base dimensions
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 at its nominal volume

3.3
cure
process of transforming uncured polymer into an elastic material through a covalent crosslinking reaction

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

3.6
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 which has been filled by the manufacturer 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 with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.10
orientation means
mark in or on the implant to assist the surgeon in positioning the implant

3.11
shell
envelope of the mammary implant

3.12
seam
seal junction of implant materials fused or adhered together

3.13
silicone elastomer
synthetic rubber obtained by the crosslinking of silica reinforced silicone polymer chains essentially made of repeat diorganosiloxane units

3.14
silicone gel
partially crosslinked silicone polymer, featuring a semisolid material consisting of crosslinked silicone polymer and liquid silicone polymer

3.15
silicone polymer
polymer chains essentially made of repeat diorganosiloxane units

3.16
supplier
company who manufactures and/or supplies the raw materials and components used for the production of mammary implants

3.17
valve
shell 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 14630:2012, Clause 4, apply.

5 Design attributes

The requirements of ISO 14630:2012, Clause 5, apply.

6 Materials

6.1 General

The requirements of ISO 14630:2012, Clause 6, apply.

— Materials shall be manufactured and tested under a quality management system.

The information stated within Clause 6 shall be available from the manufacturer.

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

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

6.2 Cytotoxicity

The components of each production raw material lot shall be cured and tested for cytotoxicity in accordance with ISO 10993-5. No cytotoxic effects shall be induced around the material tested, or throughout the culture.

6.3 Residual low molecular weight oligomers

The combined residual oligomers, cyclotetrasiloxane (D4) and cyclopentasiloxane (D5), in uncured or cured gel shall be tested in accordance with Annex A.

6.4 Trace elements

The components of each production raw material lot shall comply with the Table 1 specifications on metal impurities.

Table 1 — Metals impurities limit content

Element	Limit content [a] (mg/kg)
As, Pb, Cd, Hg, V, Mo, Se, Co, Sb, Ba, Cr, Cu, Sn, Ni	≤ 10
[a] Per element	

If one of these metals comprises part of the formulation component (for example BaSO4), it is not considered an impurity

6.5 Physico - Mechanical properties and characterization

The following mechanical characteristics of silicone elastomers, after cure shall be available for every raw material lot:

— elongation at break (%), according to ISO 37 or ASTM D412

— tensile strength at break (MPa) according to ISO 37 or ASTM D412

— modulus at 100 % elongation (MPa), according to ISO 37 or ASTM D412

— hardness (IRHD), according to ASTM D2240 or ISO 7619-1

— relative density, or specific gravity, according to ASTM D792

— tear strength (kN/m), according to ISO 34-1, Method C, or ASTM D624, Die B.

The penetration or bulk gel hardness of silicone gel, after cure shall be available for every raw material lot.

6.6 Documentation of materials

The manufacturer shall require from the supplier for each type of material, a certificate of analysis including at least the following information:

a) supplier's name, address and telephone number;

b) material reference;

c) for silicone material the range of properties (as defined in 6.5), with defined specification limits and test methods, including cure conditions. For other materials, same type of information shall be required, if applicable.

7 Design evaluation

7.1 General

The requirements of ISO 14630:2012, 7.1, apply.

The design of mammary implants shall be based on a risk assessment taking into account the fact that their benefit is deemed to be primarily aesthetic and psychological in nature, whether the application is for reconstructive and/or cosmetic purposes

7.2 Pre-clinical evaluation

7.2.1 General

The pre-clinical evaluation of mammary implants shall conform to ISO 14630:2012, 7.2 and fulfil the requirements of ISO 10993-1.

Where no test is described in this International Standard, or when the test described is not applicable, description for the alternative validated test method, test specimen preparation used and testing results shall be documented by the manufacturer. The adequacy of the pass/fail criteria adopted for the evaluation shall be verified prior to testing.

All testing samples shall be representative of finished sterilized devices.

A worst-case assumption shall be considered

The sample size selected shall be based on a statistical rationale, which shall be justified and documented.

Where appropriate, for materials other than silicone, the manufacturer shall consider and develop tests as indicated in 7.2.2 to 7.2.5.

7.2.2 Mechanical tests

7.2.2.1 Shell integrity

7.2.2.1.1 General

The integrity of the shell shall be evaluated.