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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

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

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

— limit values for trace elements have been added (6.4);

— determination of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in silicone gels (new Annex A) has been included;

— mechanical test on a mammary implant in its implantable state (new Annex C, previously Annex E), specifically the fatigue test (C.1), has undergone major revision;

— test for silicone gel penetration (silicone filling materials only) (new Annex F) has been included;

— silicone diffusion assessment from mammary implants by an *in vitro* method (new Annex G, previously Annex H) has undergone major revision;

— test for surface characteristics (new Annex H, previously Annex A) has undergone major revision.

This corrected version of ISO 14607:2018 incorporates the following corrections:

— In B.2.2, second paragraph, "shell adjacent to the bonded area," has been changed to "test specimen", "," after " Figure B.2" has been deleted , and "held" has been changed to "maintained".

— In B.2.3, first paragraph, "shell adjacent to the bonded area" has been changed to "test specimen designated l_0 in Figure B.1 and Figure B.2" and "held" has been changed to "maintained".

— “prostheses projection” has been replaced by “anterior projection” in two instances, in C.1.6 a) and C.2.5 a).

— “implant projection” has been replaced by “anterior projection” in two instances, in C.2.3 c).

— In G.2.4, first paragraph, “for meeting” has been deleted.

— In G.3.2, third paragraph, “6 Vi ± 0,03Vi” has been replaced by “6,00 Vi ± 0,03Vi”.

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 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, the lowest available level is the level to start with.

Non-active surgical implants — Mammary implants — Particular 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 34-1:2015, *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 4287, *Geometrical Product Specifications (GPS) — Surface texture: 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 11607-1, *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 14630:2012, *Non-active surgical implants — General requirements*

ASTM D412–16, *Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers — Tension*

ASTM D624–00 (2012), *Standard guide for evaluation of thermoplastic polyurethane solids and solutions for biomedical applications*

ASTM D792–13, *Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement*

ASTM D2240–15, *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.