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Non-active surgical implants — Mammary implants — Particular requirements

*Implants chirurgicaux non actifs — Implants mammaires —
Exigences particulières*



Reference number
ISO 14607:2018(E)

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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 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.

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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, " $6 V_i \pm 0,03V_i$ " has been replaced by " $6,00 V_i \pm 0,03V_i$ ".

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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 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.