INTERNATIONAL STANDARD

ISO 14607

Second edition
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14607 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in collaboration with Technical Committee ISO/TC 150, *Implants for surgery*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14607:2002), which has been technically revised.

Introduction

In addition to the requirements given in the level 1 standard, this International Standard provides a method for addressing the fundamental principles outlined in ISO/TR 14283, as they apply to non-active surgical implants. It also provides a method to demonstrate compliance with the relevant Essential Requirements as outlined in general terms in Annex I of the Directive 93/42/EEC of 14 June 1993 concerning medical devices (amended by the Commission Directive 2003/12/CE), as they apply to mammary implants for use in clinical practice.

Further specific information on mammary implants indicating how to comply with the Directive 93/42/EEC is given by the Communication from the European Commission on community and national measures in relation to mammary implants.

There are three levels of European Standards dealing with non-active surgical implants. These are as follows (with level 1 being 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 for clinical practice.

With regard to safety, this International Standard specifies requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

2 Normative references

The following referenced documents are indispensable for the application 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 34-1:2004, *Rubber, vulcanized or thermoplastic — Determination of tear strength — Part 1: Trouser, angle and crescent test pieces*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

ISO 14630:—[1)], *Non-active surgical implants — General requirements*

NF S 99-401:1994, *Medical devices — Silicone elastomer of medical grade*

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 14155-1, ISO 14155-2 and ISO 14630 and the following apply.

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

1) To be published. (Revision of ISO 14630:2005)