SLOVENSKI STANDARD
SIST EN ISO 14607:2007

01-julij-2007

Nadomeġļ a:
SIST EN 12180:2000

Neaktivni kirurški vsadki (implantati) - Prsni vsadki - Posebne zahteve (ISO 14607:2007)

Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2007)

Nichtaktive chirurgische Implantate - Mammaimplantate - Besondere Anforderungen (ISO 14607:2007)

Implants chirurgicaux non actifs - Implants mammaires - Exigences particulieres (ISO 14607:2007)

Ta slovenski standard je istoveten z: **EN ISO 14607:2007**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

SIST EN ISO 14607:2007 **en;fr;de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14607

February 2007

ICS 11.040.40

Supersedes EN 12180:2000

English Version

Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2007)

Implants chirurgicaux non actifs - Implants mammaires - Exigences particulières (ISO 14607:2007)

Nichtaktive chirurgische Implantate - Mammaimplantate - Besondere Anforderungen (ISO 14607:2007)

This European Standard was approved by CEN on 4 February 2007.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN ISO 14607:2007: E

Foreword

This document (EN ISO 14607:2007) has been prepared by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by NEN, in collaboration with Technical Committee ISO/TC 150 "Implants for surgery".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.

This document supersedes EN 12180:2000.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

ANNEX ZA
(informative)

Relationship between this International Standard and the Essential Requirements of EU Directive 93/42/EEC Medical Devices

This International Standard has been prepared under a mandate given to CEN by the European Commission to provide one means of conforming to the Essential Requirements of the New Approach Directive 93/42/EEC Medical Devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC Medical Devices

Clause(s)/sub-clause(s) of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4	1 - 2 - 3 - 4 - 7.1	
5	1 - 2 - 3 - 4 - 5 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
6	1 - 2 - 7.1 - 7.2 - 7.3 - 7.4 - 7.5 - 8.2 - 9.2	
7	1 - 2 - 3 - 4 - 5 - 6 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2 - 14	
8	1 - 2 - 3 - 5 - 7.1 - 7.2	
9	1 - 2 - 7.2 - 8.1 - 8.3 - 8.4	
10	1 - 2 - 3 - 5 - 7.2 - 8.3 - 8.6	
11	1 - 2 - 13	11.6 requires that the information detailed in Annex F be given to the patient by the medical staff, in accordance with the Essential Requirements 13.6 k) and l).

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

INTERNATIONAL STANDARD

ISO 14607

Second edition
2007-02-15

Non-active surgical implants — Mammary implants — Particular requirements

Implants chirurgicaux non actifs — Implants mammaires — Exigences particulières

Reference number
ISO 14607:2007(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword ... iv

Introduction ... v

1 Scope ... 1

2 Normative references ... 1

3 Terms and definitions ... 1

4 Intended performance ... 2

5 Design attributes ... 2

6 Materials ... 3

7 Design evaluation ... 3
7.1 General ... 3
7.2 Pre-clinical evaluation ... 3
7.3 Clinical evaluation ... 6
7.4 Post-market surveillance ... 7

8 Manufacturing ... 7

9 Sterilization ... 7

10 Packaging ... 7

11 Information supplied by the manufacturer ... 7
11.1 General ... 7
11.2 Resterilization ... 8
11.3 Base dimensions ... 8
11.4 Effects on diagnostic techniques ... 8
11.5 Filling materials ... 8
11.6 Information on expected lifetime ... 8
11.7 Information for the patient ... 8
11.8 Labels ... 9
11.9 Information for the user ... 9
11.10 Marking on implants ... 9
11.11 Manufacturer's device card ... 9

Annex A (normative) **Test for surface characteristics** ... 10

Annex B (normative) **Tests for shell integrity** ... 11

Annex C (normative) **Test method for valve competence and injection site competence** ... 13

Annex D (normative) **Test for silicone gel cohesion (silicone filling materials only)** ... 15

Annex E (normative) **Mechanical tests on a mammary implant in its implantable state** ... 17

Annex F (normative) **Information for the patient** ... 22

Annex G (normative) **Information for the user** ... 24

Annex H (informative) **Silicone release assessment from mammary implants by an in vitro method** ... 25

Bibliography ... 28

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)