

# Non-active surgical implants — Body contouring implants — Specific requirements for mammary implants

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# National foreword

This British Standard is the official English language version of EN 12180:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/19, Reconstructive surgical implants, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

## Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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## Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 22, an inside back cover and a back cover.

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English version

## Non-active surgical implants – Body contouring implants – Specific requirements for mammary implants

Implants chirurgicaux non actifs – Implants morphologiques  
– Exigences spécifiques relatives aux implants mammaires

Nichtaktive chirurgische Implantate – Weichteilimplantate –  
Besondere Anforderungen an Mammaimplantate

This European Standard was approved by CEN on 29 October 1999.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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## Foreword

This European Standard has been prepared by Technical Committee CEN/TC 285, Non-active surgical implants, the Secretariat of which is held by NNI.

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 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.

This European Standard 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 standard.

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 3 standard and contains requirements that apply to specific types of implants within a family.

The Level 1 standard, EN 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.

The Level 2 standards apply to a more restricted set or family of implants such as those designed for use in osteosynthesis, cardiovascular surgery, or joint replacement.

Level 2 standards contain requirements that apply to all non-active surgical implants in particular families of implants.

NOTE: A Level 2 standard on body contouring implants is currently in preparation.

To address all requirements, it is necessary to start with a standard of the lowest available level.

References to other European or international standards can also be found in the Bibliography

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

## Introduction

This European Standard provides, in addition to the requirements in the Level 1 and Level 2 standards, a method to demonstrate compliance with the relevant Essential Requirements (ERs) as outlined in general terms in Annex I of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to body contouring implants, specifically mammary implants for use in clinical practice.

## 1 Scope

This standard describes specific requirements for mammary implants for clinical practice.

With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

NOTE: At the time of publication of this document for enquiry several test methods specified in the annexes were being validated. For the time being, where appropriate, disclosure statements are included in these annexes.

## 2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

|                   |                                                                                                                          |
|-------------------|--------------------------------------------------------------------------------------------------------------------------|
| EN ISO 14630:1997 | Non-active surgical implants - General requirements (ISO 14630:1997)                                                     |
| NF T 46-002       | Vulcanized or thermoplastic rubber - Tensile test                                                                        |
| NF T 46-007       | Vulcanized rubbers - Determination of tear strength (angle tear test piece with or without nick and crescent test piece) |
| NF S 99-401       | Medical devices - Silicone elastomer of medical grade                                                                    |

NOTE: The Bibliography gives informative references to other useful standards.

### 3 Definitions

For the purposes of this standard the definitions in EN ISO 14630:1997 apply together with the following:

**3.1 mammary implant:** Implant designed to add to or replace volume of the breast.

**3.2 shell:** Envelope of the implant.

**3.3 seams or seals:** Junction of materials fused or adhered together.

**3.4 valve:** Component into which an accessory is inserted to inflate variable volume implants.

**3.5 injection site:** Component designed to be penetrated by a needle to alter the volume of the implant.

**3.6 diffusion:** Movement of material out of an implant through an intact shell.

**3.7 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.

**3.8 anterior projection:** Maximum height of the implant when placed with its base on a flat horizontal surface at its nominal volume.

**3.9 orientation means:** Mark in or on the implant to assist the surgeon to position the implant.

### 4 Intended performance

The requirements of clause 4 of EN ISO 14630:1997 apply.

### 5 Design attributes

The requirements of clause 5 of EN ISO 14630:1997 apply.

### 6 Materials

The requirements of clause 6 of EN ISO 14630:1997 apply. In addition, if silicone elastomer is used, NF S 99-401 applies.

Special attention shall be given to the biological evaluation of the device and its components following implant failure.

NOTE: The biological evaluation should be in accordance with the principles set out in EN ISO 10993-1.

## 7 Design evaluation

The requirements of clause 7 of EN ISO 14630:1997 apply.

### 7.1 Pre-clinical evaluation

The pre-clinical evaluation of mammary implants shall conform to 7.2 of EN ISO 14630:1997.

NOTE 1: With regard to validated test methods available for the pre-clinical evaluation this standard reflects the present state of the art. Tests for the evaluation of abrasion of mammary implants and for the evaluation of gel bleeding of mammary implants in vitro are currently under development. As soon as acceptable and validated test methods are available these will be considered for inclusion in this standard by an amendment or revision.

The sample size selected shall be based on a statistical rationale which shall be justified and documented. In addition the following shall be addressed (where applicable):

NOTE 2: Where appropriate, for materials other than silicone the manufacturer should consider and develop tests as indicated in 7.1.

#### 7.1.1 Shell integrity

The integrity of the shell shall be evaluated.

The integrity of the silicone elastomer shall be tested in accordance with Annex B and shall comply with the stated requirements.

NOTE: For other materials, it is recommended that tests with similar conditions are developed.

#### 7.1.2 Valve or injection site competence

The competence of the valve or injection site shall be tested in accordance with Annex C and shall comply with the stated requirements.

#### 7.1.3 Silicone gel

The cohesion of silicone gel shall be tested in accordance with Annex D and shall comply with the stated requirements.

#### 7.1.4 Mechanical tests

Mechanical tests shall be conducted in accordance with Annex E and shall comply with the stated requirements.

**7.1.4.1 Fatigue test** The fatigue test shall be conducted in accordance with Annex E.1. After testing, the shell of the implant shall not present any tears, cracks or cuts when examined under x10 magnification.

**7.1.4.2 Impact resistance test** Impact resistance test shall be conducted in accordance with Annex E.2 and shall comply with the stated requirements.

**7.1.4.3 Diffusion test** Gel diffusion shall be evaluated.

NOTE 1: No validated test method is currently available. The test method and requirements for this clause are under consideration.

NOTE 2: Where no test method is described in this standard, description of the validated test method and sample preparation used should be documented by the manufacturer.