National Standards Authority of Ireland

IRISH STANDARD

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NON-ACTIVE SURGICAL IMPLANTS - BODY CONTOURING IMPLANTS - SPECIFIC REQUIREMENTS FOR MAMMARY IMPLANTS

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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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPAISCHES KOMITEE FUR NORMUNG

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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of an identical text or by endorsement, at the latest by August 2000, and conflicting national standards shall be withdrawn at the latest by August 2000.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 under 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.