National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 14607:2007

ICS 11.040.40

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NON-ACTIVE SURGICAL IMPLANTS - MAMMARY IMPLANTS - PARTICULAR REQUIREMENTS (ISO 14607:2007)

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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

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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of an identical text or by endorsement, at the latest by August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.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.