



SLOVENSKI STANDARD
kSIST prEN ISO 14607:2009
01-marec-2009

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 particulières (ISO 14607:2007)

Ta slovenski standard je istoveten z: prEN ISO 14607

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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kSIST prEN ISO 14607:2009

en

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 14607

December 2008

ICS 11.040.40

Will supersede EN ISO 14607:2007

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 draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 285.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



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

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Foreword

The text of ISO 14607:2007 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as prEN ISO 14607:2008 by Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede EN ISO 14607:2007.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

Endorsement notice

The text of ISO 14607:2007 has been approved by CEN as a prEN ISO 14607:2008 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on 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 clauses of this standard given in table ZA 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 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of 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 - 6.a - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
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	<p>Subclause 11.7 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).</p> <p>The part of ER 13.3.a concerning the information on the authorized representative is not addressed in this European Standard</p> <p>ER 13.6.q) This relevant Essential Requirement is not addressed in this European Standard.</p>
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WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

