SLOVENSKI STANDARD
SIST EN ISO 14630:2013

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Nadomešča:
SIST EN ISO 14630:2009

Neaktivni kirurški vsadki (implantati) - Splošne zahteve (ISO 14630:2012)

Non-active surgical implants - General requirements (ISO 14630:2012)

Nichtaktive chirurgische Implantate - Allgemeine Anforderungen (ISO 14630:2012)

Implants chirurgicaux non actifs - Exigences générales (ISO 14630:2012)

Ta slovenski standard je istoveten z: **EN ISO 14630:2012**

ICS:

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

SIST EN ISO 14630:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14630

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Supersedes EN ISO 14630:2009

English Version

Non-active surgical implants - General requirements (ISO 14630:2012)

Implants chirurgicaux non actifs - Exigences générales (ISO 14630:2012)

Nichtaktive chirurgische Implantate - Allgemeine Anforderungen (ISO 14630:2012)

This European Standard was approved by CEN on 30 November 2012.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 14630:2012) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 14630:2009.

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.

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Endorsement notice

The text of ISO 14630:2012 has been approved by CEN as a EN ISO 14630:2012 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 Union 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.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 European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2nd indent	
4, 5, 8 and 10	5	
7.1 and 7.2	6a	
5 a), 5 l), 6 a) and 6 b)	7.1, 1st indent	
5 a), 6 a) and 6 b)	7.1, 2nd indent	
7.2 c)	7.1, 3rd indent	
5 f), 5 r), 7, 8 and 10	7.2	
5 h) and 6	7.3	
6	7.4	
5 d), 5 e) and 6	7.5	
5 b), 5 f), 5 m) and 6	7.6	
5 q), 6, 8, 9.1 and 10.1	8.1	
6	8.2	
10.2	8.3	
9.2	8.4	
5 g), 8 and 9.3	8.5	
9.1 and 10.1	8.6	
11.2 f) and 11.3 j)	8.7	
5 i), 5 j) and 11.4	9.1	
5 b), 5 k), 6 and 7.1	9.2, 1st indent	
5 n), 6 and 7.1	9.2, 2nd indent	
5 n)	9.2, 3rd indent	
5 c), 5 d) and 6	9.2, 4th indent	
11.1, 11.2, 11.3 b), g), h) and 11.5	13.1	

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11.1	13.2	
11.2 b)	13.3 a)	
11.2 c) and 11.2 d)	13.3 b)	
11.2 e)	13.3 c)	
11.2 c)	13.3 d)	
11.2 g)	13.3 e)	
11.2 h)	13.3 f)	
11.6	13.3 g)	
11.6	13.3 h)	
10.1 and 11.2 j)	13.3 i)	
11.2 j)	13.3 j)	
11.2 k)	13.3 k)	
11.2 e)	13.3 m)	
11.2 d) and 11.3 d)	13.4	
4 and 11.2 c)	13.5	
11.3 b), c), d), i), m), n) and 11.6	13.6 a)	
11.3 e)	13.6 b)	
11.3 f) and 11.4	13.6 c)	
11.3 h)	13.6 d)	
11.3 g) and o)	13.6 e)	
11.3 q), r) and t), Indent 5	13.6 f)	
9.3.2, 10.2 and 11.3 l)	13.6 g)	
9.3 and 11.2 k)	13.6 i)	
11.3 a)	13.6 j)	
11.3 b) and t), Indent 3	13.6 k)	
11.3 t), Indents 1, 2 and 4	13.6 l)	
11.3 t), Indent 6	13.6 m)	
11.3 s)	13.6 n)	
11.3 u)	13.6 q)	

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

INTERNATIONAL STANDARD

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Non-active surgical implants — General requirements

Implants chirurgicaux non actifs — Exigences générales

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