SLOVENSKI STANDARD
kSIST prEN ISO 14602:2009

01-marec-2009

Neaktivni kirurški vsadki (implantati) - Vsadki za osteosintezo - Posebne zahteve (ISO 14602:1998)

Non-active surgical implants - Implants for Osteosynthesis - Particular requirements (ISO 14602:1998)

Nichtaktive chirurgische Implantate - Implantate zur Osteosynthese - Besondere Anforderungen (ISO 14602:1998)

Implants chirurgicaux non actifs - Implants pour ostéosynthèse - Exigences particulières (ISO 14602:1998)

Ta slovenski standard je istoveten z: **prEN ISO 14602**

ICS:

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

kSIST prEN ISO 14602:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 14602

December 2008

ICS 11.040.40

Will supersede EN ISO 14602:1998

English Version

Non-active surgical implants - Implants for Osteosynthesis - Particular requirements (ISO 14602:1998)

Implants chirurgicaux non actifs - Implants pour ostéosynthèse - Exigences particulières (ISO 14602:1998)

Nichtaktive chirurgische Implantate - Implantate zur Osteosynthese - Besondere Anforderungen (ISO 14602:1998)

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 14602:1998 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 14602:2008 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 14602:1998.

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 14602:1998 has been approved by CEN as a prEN ISO 14602:2008 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, 4.1, 4.2, 4.3	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.4	This clause 4 has been detailed in consideration of the complexity related to osteosynthesis Part of ER 1 relating to risk of use error is not addressed in this European Standard. Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision. The part of ER 7.1 relating to biophysical or modelling research is partly addressed by this European Standard. Note: validated modelling is an important issue for joint replacement implants and should be addressed during the next revision. The part of ER 7.4 relating to the regulatory provisions for the verification of the medicinal product is not addressed by this European Standard.
5, 5.1, 5.2	1, 2, 3, 4, 5, 7.1, 7.2, 7.3, 7.6, 8, 9.1	Most of the requirements are covered in the level 1 standard EN ISO 14630:1997. The additional requirements of this standard, clauses 5.1 and 5.2 are added to draw particular attention to interconnecting implant systems and the physiological environment. The part of ER 1 relating to risk of use error is not addressed in this European Standard.

		Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision. The part of ER 7.1 relating to biophysical or modelling research is partly addressed by this European Standard. Note: validated modelling is an important issue for joint replacement implants and should be addressed during the next revision.
6	1, 2, 7.1, 7.2, 7.3, 7.4, 7.5, 8.2, 9.2	This clause 6 refers entirely to the content of the level 1 standard EN ISO 14630:1997, but gives an annex B an informative list of ISO standards related to materials found acceptable for implants for osteosynthesis through proven clinical use. The part of ER 1 relating to risk of use error is not addressed in this European Standard. Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision. The part of ER 7.1 relating to biophysical or modelling research is partly addressed by this European Standard. Note: validated modelling is an important issue for joint replacement implants and should be addressed during the next revision. The part of ER 7.4 relating to the regulatory provisions for the verification of the medicinal product is not addressed by this European Standard.
7, 7.1, 7.2	1, 2, 3, 4, 6, 7.1, 7.2, 7.3, 7.4, 7.6, 9.2	Clause 7 adds mainly features to the testing aspect of implants for osteosynthesis, otherwise EN ISO 14630:1997 applies The part of ER 1 relating to risk of use error is not addressed in this European Standard. Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision. ER 6.a) on clinical evaluation is not addressed by this European Standard. Note: this should be addressed during the next revision. The part of ER 7.1 relating to biophysical or modelling research is partly addressed by this European Standard. Note: validated modelling is an important issue for

		joint replacement implants and should be addressed during the next revision. The part of ER 7.4 relating to the regulatory provisions for the verification of the medicinal product is not addressed by this European Standard.
8	1, 2, 3, 5, 7.1, 7.2	The requirements of the level 1 standard EN ISO 14630:1997 apply, no requirements were added in this level 2 standard The part of ER 1 relating to risk of use error is not addressed in this European Standard. Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision. The part of ER 7.1 relating to biophysical or modelling research is partly addressed by this European Standard. Note: validated modelling is an important issue for joint replacement implants and should be addressed during the next revision.
9	1, 2, 7.2, 8, 8.1, 8.3, 8.4	The requirements of the level 1 standard EN ISO 14630:1997 apply, no requirements were added in this level 2 standard The part of ER 1 relating to risk of use error is not addressed in this European Standard. Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision.
10	1, 2, 3, 5, 7.2, 8, 8.4	The requirements of the level 1 standard EN ISO 14630:1997 apply, no requirements were added in this level 2 standard The part of ER 1 relating to risk of use error is not addressed in this European Standard. Note: Ergonomic features are an important issue for joint replacement implants and should be addressed during the next revision.
11	1, 2, 8.7, 9.1, 13	Part of 13 3 a relating to the authorised representative is not covered by this European Standard. In clause 11 of this standard some relevant requirements are added to the general requirements of EN ISO 14630:1997 The part of ER 1 relating to risk of use error is not