



SLOVENSKI STANDARD
SIST EN ISO 16054:2002
01-november-2002

Vsadki (implantati) za kirurgijo - Najmanjša garnitura za kirurške vsadke (implantate) (ISO 16054:2000)

Implants for surgery - Minimum data sets for surgical implants (ISO 16054:2000)

Chirurgische Implantate - Mindestdatensätze für chirurgische Implantate (ISO 16054:2000)

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Implants chirurgicaux - Ensembles minimaux de données relatives aux implants chirurgicaux (ISO 16054:2000)

[SIST EN ISO 16054:2002](https://standards.iteh.ai/catalog/standards/sist/89ea066a-3c93-4c59-8ef7-146dc5dc02f8/sist-en-iso-16054-2002)

Ta slovenski standard je istoveten z: EN ISO 16054:2002

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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SIST EN ISO 16054:2002

en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 16054

May 2002

ICS 11.040.40

English version

Implants for surgery - Minimum data sets for surgical implants (ISO 16054:2000)

Implants chirurgicaux - Ensembles minimaux de données
relatives aux implants chirurgicaux (ISO 16054:2000)

Chirurgische Implantate - Mindestdatensätze für
chirurgische Implantate (ISO 16054:2000)

This European Standard was approved by CEN on 11 April 2002.

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 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 Management Centre 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

EN ISO 16054:2002 (E)

CORRECTED 2002-06-19

Foreword

The text of the International Standard from Technical Committee ISO/TC 150 "Implants for surgery" of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by NEN.

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 November 2002, and conflicting national standards shall be withdrawn at the latest by November 2002.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Endorsement notice
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The text of the International Standard ISO 16054:2000 has been approved by CEN as a European Standard without any modification. [ISO 16054:2002](https://standards.iteh.ai/catalog/standards/sist/89ea066a-3c93-4c59-8ef7-011111111111/iso-16054-2000)

[https://standards.iteh.ai/catalog/standards/sist/89ea066a-3c93-4c59-8ef7-](https://standards.iteh.ai/catalog/standards/sist/89ea066a-3c93-4c59-8ef7-011111111111/iso-16054-2002)

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA (normative)

Normative references to international publications with their relevant European publications

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 (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 13485	1996	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9001	EN ISO 13485	2000

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INTERNATIONAL STANDARD

**ISO
16054**

First edition
2000-12-15

Implants for surgery — Minimum data sets for surgical implants

*Implants chirurgicaux — Ensembles minimaux de données relatives aux
implants chirurgicaux*

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f4bde3deb2f8/sist-en-iso-16054-2002](https://standards.iteh.ai/catalog/standards/sist/89ea066a-3c93-4c59-8ef7-f4bde3deb2f8/sist-en-iso-16054-2002)



Reference number
ISO 16054:2000(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 16054 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Annex A of this International Standard is for information only.

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