



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN ISO 16054:2002

ICS 11.040.40

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**IMPLANTS FOR SURGERY - MINIMUM DATA
SETS FOR SURGICAL IMPLANTS
(ISO 16054:2000)**

*This Irish Standard was
published under the
authority of the National
Standards Authority of
Ireland
and comes into effect on
September 13 2002*

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Údarás um Chaighdeán Náisiúnta na hÉireann

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.



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

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EN ISO 16054:2002 (E)

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.

Endorsement notice

The text of the International Standard ISO 16054:2000 has been approved by CEN as a European Standard without any modification.

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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