Irish Standard
I.S. EN ISO 16054:2019

Implants for surgery - Minimum data sets for surgical implants (ISO 16054:2019)

I.S. EN ISO 16054:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:	*Published:*
EN ISO 16054:2019	2019-07-17

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2019-08-04	11.040.40
	NOTE: If blank see CEN/CENELEC cover page

NSAI	T +353 1 807 3800	Sales:
1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
Northwood, Santry	E standards@nsai.ie	F +353 1 857 6729
Dublin 9	W NSAI.ie	W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

National Foreword

I.S. EN ISO 16054:2019 is the adopted Irish version of the European Document EN ISO 16054:2019, Implants for surgery - Minimum data sets for surgical implants (ISO 16054:2019)

This document does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

For relationships with other publications refer to the NSAI web store.

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This page is intentionally left blank

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 16054

July 2019

ICS 11.040.40

Supersedes EN ISO 16054:2002

English Version

Implants for surgery - Minimum data sets for surgical implants (ISO 16054:2019)

Implants chirurgicaux - Ensembles minimaux de données relatives aux implants chirurgicaux (ISO 16054:2019)

Chirurgische Implantate - Mindestdatensätze für chirurgische Implantate (ISO 16054:2019)

This European Standard was approved by CEN on 23 June 2019.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 16054:2019 E

Contents

Page

European foreword

This document (EN ISO 16054:2019) 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 January 2020, and conflicting national standards shall be withdrawn at the latest by January 2020.

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

This document supersedes EN ISO 16054:2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 16054:2019 has been approved by CEN as EN ISO 16054:2019 without any modification.

This page is intentionally left blank

I.S. EN ISO 16054:2019

INTERNATIONAL STANDARD

ISO 16054

Second edition
2019-07

Implants for surgery — Minimum data sets for surgical implants

Implants chirurgicaux — Ensembles minimaux de données relatives aux implants chirurgicaux

Reference number
ISO 16054:2019(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery.*

This second edition cancels and replaces the first edition (ISO 16054:2000), which has been technically revised. The main changes compared to the previous edition are as follows:

— clarification to definitions with the provision of specific examples of the defined terms;

— updated general requirements for data sets with direction on what constitutes an individual implant;

— inclusion of GTIN and UDI as options for implant identification in data items lists;

— inclusion of expiry date and date of acquisition in supplier data items list;

— defined requirements for data maintenance for medical facilities;

— separated data item lists for medical facilities concerning implant and explant events and identified items specific to each type of event;

— included cause and situation in the data item list of an explant event;

— updated reference list in Annex A.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The importance and utility of registry, tracking and retrieval analysis systems in understanding long term clinical performance of implants and in patient follow up in the event of unforeseen implant malfunction is understood.

This document specifies the minimum data collection requirements for the purpose of implant tracking to allow recall for product correction or patient follow up in the event of unforeseen device malfunction. The minimum data set also fulfils the core data requirements to allow cross referencing between extended data sets for the purposes of retrieval analysis and research.

It is possible to collect all the data items specified in this document and, if desired, to transfer them to third party registers using automated methods. Annex A and the Bibliography provide references to technical standards which define mechanisms for automation of both data collection and transmission. Annex A is for information only.

Implants for surgery — Minimum data sets for surgical implants

1 Scope

This document defines minimum data sets for implants to facilitate recording and international exchange of data for the purposes of implant tracking systems. This data can also be used to support retrieval analysis and implant registry.

This document is applicable to the manufacturers and distributors of medical devices intended for implant via a surgical procedure and to those hospitals and other medical facilities which carry out implant or explant procedures. It specifies requirements for data items to be recorded by the manufacturers and distributors of implants and by hospitals and other medical facilities at both the time of implant event and at the time of any subsequent explant event.

This document is intended to define a minimum data set to be recorded for all implant and explant events, as well as providing for the timely retrieval of minimum implant data related to specific subsets of patients who have received specific identified devices or devices within a specified range of lot, batch or serial codes, for the purpose of patient follow up.

It is not the intent of this document to provide a means of data recovery which is related to specific medical practitioners, medical facilities or manufacturers for purposes other than patient follow up or product recall in the event of unforeseen device malfunction.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
implant
device that is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place after the procedure, or any medical device that is intended to be partially introduced into the human body by means of surgical intervention and that is intended to remain in place after the procedure for at least 30 days

Note 1 to entry: Note to entry: In this document, the term "implant" refers to each individual component of a system or a modular implant, provided separately or as a kit, as well as all ancillary implants or associated implants required for the implant event.

[SOURCE: ISO 14630:2012, 3.8, modified — The words "surgical implant" have been changed to "implant". Note to entry added.]