SLOVENSKI STANDARD
SIST EN ISO 14708-3:2023

01-junij-2023

Vsadki (implantati) za kirurgijo - Aktivni medicinski pripomočki za vsaditev - 3. del: Vsadljivi nevrostimulatorji (ISO 14708-3:2017)

Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO 14708-3:2017)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 3: Implantierbare Neurostimulatoren (ISO 14708-3:2017)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 3: Neurostimulateurs en implant (ISO 14708-3:2017)

Ta slovenski standard je istoveten z: **EN ISO 14708-3:2022**

ICS:

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

SIST EN ISO 14708-3:2023 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14708-3

July 2022

ICS 11.040.40

English version

Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO 14708-3:2017)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 3: Neurostimulateurs en implant (ISO 14708-3:2017)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 3: Implantierbare Neurostimulatoren (ISO 14708-3:2017)

This European Standard was approved by CEN on 6 July 2022.

CEN and CENELEC 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 and CENELEC 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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees 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, Türkiye and United Kingdom.

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

Contents

Page

European foreword

This document (EN ISO 14708-3:2022) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN-CENELEC/ JTC 16 “Active Implantable Medical Devices” the secretariat of which is held by DKE.

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 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.

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

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 14708-3:2017 has been approved by CEN-CENELEC as EN ISO 14708-3:2022 without any modification.

INTERNATIONAL STANDARD

ISO 14708-3

Second edition
2017-04

Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 3: Neurostimulateurs en implant

Reference number
ISO 14708-3:2017(E)

COPYRIGHT PROTECTED DOCUMENT

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

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,* SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-3:2008), which has been technically revised.

A list of all parts in the ISO 14708 series can be found on the ISO website.

Introduction

This document specifies particular requirements for active implantable medical devices intended for electrical stimulation of the central or peripheral nervous system, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014, hereinafter referred to as ISO 14708-1.

The requirements of this document take priority over those of ISO 14708-1.

Devices that use electricity to stimulate the nervous system are commonly called “neurostimulators.” They produce controlled electrical pulses that are delivered through electrodes in contact with a specific target area. Whether or not a neurostimulator is totally or partially implantable, a lead or extension is usually required to convey stimulation pulses from a form of pulse generator to the electrodes, although newer forms of devices might not utilize leads or extensions. An external programmer might be used to adjust device parameters.

Currently, several types of neurostimulators exist for treating the central or peripheral nervous system. This document is intended to apply to these neurostimulator types regardless of therapy.

This document is relevant to all parts and accessories of implantable neurostimulators, including programmers, software, and technical manuals. Not all parts or accessories might be intended to be totally or partially implanted, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance intended by the manufacturer.

Not included in the scope of this document are non-implantable medical devices, such as external neurostimulators and RF-coupled neurostimulators, even though such devices might have implantable parts, because they are covered under the IEC 60601-1 series of standards.

Within this document, the following terms are used to amend and supplement ISO 14708-1:

“Replacement”: the clause of ISO 14708-1 is replaced completely by the text of this document.

“Addition”: the text of this document is additional to the requirements of ISO 14708-1.

“Amendment”: the clause of ISO 14708-1 is amended as indicated by the text of this document.

“Not used”: the clause of ISO 14708-1 is not applied in this document.

Subclauses, figures, or tables that are additional to those of ISO 14708-1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

Implants for surgery — Active implantable medical devices —

Part 3: Implantable neurostimulators

1 Scope

This document is applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES intended for electrical stimulation of the central or peripheral nervous system.

The tests that are specified in this document are type tests and are to be carried out on a sample of a device to assess device behavioural responses, and are not intended to be used for the routine testing of manufactured products.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14117:2012, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices*

ISO 14708-1:2014, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO/TS 10974:—[1)], *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 61000-4-3:2006+A1:2007+A2:2010, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and the following apply.

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

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

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

1) Under preparation.

3.101
implantable neurostimulator
INS
active implantable medical device intended for electrical stimulation of the central or peripheral nervous system

Note 1 to entry: For the purposes of this document, an implantable neurostimulator can be a single article, or a system consisting of a set of components and accessories which interact to achieve the performance intended by the manufacturer. Not all of these components or accessories might be required to be partially or totally implanted, e.g. programmers.

3.102
implantable pulse generator
IPG
part of an *implantable neurostimulator* (3.101), consisting of a power source and electronic circuit, which produces a stimulation voltage or current pulse

3.103
MR Conditional
item with demonstrated safety in the MR environment within defined conditions

Note 1 to entry: Adapted from ASTM F2503, 3.1.11.

3.104
projected service life
period after implantation when the *implantable neurostimulator* (3.101) remains within stated specifications and characteristics

3.105
DUT
device under test
device being tested, including conductive leads

Note 1 to entry: Not all tests require conductive leads.

4 Symbols and abbreviated terms

This clause of ISO 14708-1 applies.

5 General requirements for active implantable medical devices

This clause of ISO 14708-1 applies, except as follows.

Additional subclause:

5.101 Wireless coexistence and wireless quality of service

When communication with the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE is provided through wireless communication channels, the MANUFACTURER shall evaluate wireless coexistence and wireless quality of service through the RISK MANAGEMENT PROCESS and apply the appropriate RISK CONTROL measures to protect the patient from HARM (see 28.105).

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

6 Requirements for particular ACTIVE IMPLANTABLE MEDICAL DEVICES

No additional requirements are specified in this clause.

7 General arrangement of the packaging

This clause of ISO 14708-1 applies.

8 General markings for ACTIVE IMPLANTABLE MEDICAL DEVICES

This clause of ISO 14708-1 applies.

9 Markings on the sales packaging

This clause of ISO 14708-1 applies.

10 Construction of the sales packaging

This clause of ISO 14708-1 applies.

11 Markings on the sterile pack

This clause of ISO 14708-1 applies.

12 Construction of the non-reusable pack

This clause of ISO 14708-1 applies.

13 Markings on the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

14 Protection from unintentional biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

15 Protection from harm to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

16 Protection from harm to the patient caused by electricity

This clause of ISO 14708-1 applies.

17 Protection from harm to the patient caused by heat

This clause of ISO 14708-1 applies except as follows.

17.1

Replacement: