ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Október 2022

| STN | **Chirurgické implantáty<br>Aktívne implantovateľné zdravotnícke pomôcky<br>Časť 4: Systémy implantovateľných infúznych púmp (ISO 14708-4: 2022)** | **STN<br>EN ISO 14708-4**<br><br>85 3001 |
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Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pump systems (ISO 14708-4:2022)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 09/22

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 14708-4

July 2022

ICS 11.040.40

English version

# Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pump systems (ISO 14708-4:2022)

Implants chirurgicaux - Dispositifs médicaux implantables actifs - Partie 4: Systèmes de pompe à perfusion implantables (ISO 14708-4:2022)

Chirurgische Implantate - Aktive implantierbare medizinische Geräte - Teil 4: Implantierbare Infusionspumpen (ISO 14708-4:2022)

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

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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.

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**Rue de la Science 23, B-1040 Brussels**

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## European foreword

This document (EN ISO 14708-4:2022) 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of an identical text or by endorsement, at the latest by January 2023, and conflicting national standards shall be withdrawn at the latest by January 2023.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 14708-4:2022 has been approved by CEN-CENELEC as EN ISO 14708-4:2022 without any modification.

INTERNATIONAL STANDARD

**ISO 14708-4**

Second edition
2022-02

# Implants for surgery — Active implantable medical devices —

## Part 4: Implantable infusion pump systems

*Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 4: Systèmes de pompe à perfusion implantables*

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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.

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 of 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery,* SC 6, *Active implants,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/JTC 16, *Active implantable medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 14708-4:2008), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the title of this document has been modified;

— 9.4 additions have been deleted;

— 11.101 has been deleted;

— 14.2 replacement has been deleted;

— 14.101 has been deleted;

— 14.5 has been added;

— Clause 17 has been revised;

— 19.2 replacement has been deleted;

— 19.3 replacement has been deleted;

— 19.101 has been deleted;

— 19.7 has been added;

— 23.2 amendment has been deleted;

— Clause 27 has been revised;

— 28.8 additions have been deleted;

— 28.10 additions have been deleted;

— 28.12 addition has been deleted;

— 28.101 through 28.103 has been deleted;

— 28.31 and 28.32 has been added.

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

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

An *implantable infusion pump system* is a device that delivers either a constant infusion rate or a variable infusion rate from which a medicinal substance is delivered via an implanted catheter to site-specific locations within the human body. An external programmer might be used to adjust device parameters.

Requirements for physiologic sensing functions of *implantable infusion pump systems* are not included in this edition of this document but might be considered in future editions.

**INTERNATIONAL STANDARD** **ISO 14708-4:2022(E)**

# Implants for surgery — Active implantable medical devices —

# Part 4: Implantable infusion pump systems

## 1 Scope

This document specifies particular requirements for active implantable medical devices intended to deliver a medicinal substance to site-specific locations within the human body, to provide basic assurance of safety for both patients and users. It amends and supplements ISO 14708-1:2014. The requirements of this document take priority over those of ISO 14708-1.

This document is applicable to active implantable medical devices intended to deliver medicinal substances to site-specific locations within the human body.

This document is also applicable to some non-implantable parts and accessories of the devices defined in Clause 3.

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

NOTE This document is not intended to apply to non-implantable infusion systems.

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

ISO/TS 10974, *Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device*

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

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

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4–3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*