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28 March 2024

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

शल्य चिकित्सा हेतु प्रत्यारोपण - प्रत्यारोपण योग्य सक्रिय जैव चिकित्सा उपकरण – खंड - 4 : प्रत्यारोपण योग्य आसव पंप प्रणाली

(ISO 14708-4:2022)

Draft Indian Standard
Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pump systems

(ISO 14708-4:2022)

[ICS 11.040.40]

Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06)	Last Date for Comments: 29 April 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Standard*	*Degree of Equivalence*
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	IS/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 (First Revision)	Identical under single numbering
IEC 60601-1, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1) : 2024 IEC 60601-1 : 2020 MOD Medical electrical equipment: Part 1 General requirements for basic safety and essential performance	Modified
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	IS 13450 (Part 1/Sec 2) : 2018 IEC 60601-1-2 : 2014 Medical electrical equipment: Part 1 general requirements for the basic safety and essential performance: Sec 2 collateral standard: electromagnetic disturbances - Requirements and tests (First Revision)	Identical under dual numbering
IEC 61000-4-3, Electromagnetic compatibility (EMC) — Part 4–3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test	IS 14700 (Part 4/Sec 3) : 2023 IEC 61000-4-3: 2020 Electromagnetic compatibility EMC Part 4 Testing and Measurement Techniques Section 3 Radiated radio-frequency electromagnetic field immunity test Second Revision	Identical under dual numbering
ISO/TS 10974, Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	IS/ISO/TS 10974 : 2018 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device	Identical under single numbering

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A.

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.

NATIONAL ANNEX A
(National Foreword)

A-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 14708-4:2022 or kindly contact:

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