**Doc: MHD02(25919)WC**
**June 2024**

**BUREAU OF INDIAN STANDARDS**

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*भारतीय मानक मसौदा*

# गैर-सक्रिय सर्जिकल प्रत्यारोपण के साथ उपयोग के लिए उपकरण - सामान्य आवश्यकताएँ

*Draft Indian Standard*

# Instruments for Use in Association with Non-Active Surgical Implants — General Requirements

ICS 11.040.40, 11.040.99

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|---|---|
| Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02 | Last date for comments: **20 July 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 terminologies and 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 places, are listed below along with their degree of equivalence for the editions indicated:

| *International Standard* | *Corresponding Indian Standard* | *Degree of Equivalence* |
|---|---|---|
| ISO 8601-1<br>Date and time — Representations for information interchange — Part 1: Basic rules | IS/ISO 8601-1: 2019<br>Date and Time Representations For Information Interchange Part 1: Basic Rules | Identical |
| ISO 10993-1<br>Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process | IS 17932 (Part 1): 2023<br>Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process | Modified |
| ISO 11135<br>Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices | IS/ISO 11135: 2014<br>Sterilization of health - Care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices | Identical |
| ISO 11137-1<br>Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices | IS/ISO 11137-1: 2006<br>Sterilization of health care products - Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices | Identical |
| ISO 11137-2 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose | IS/ISO 11137-2: 2013<br>Sterilization of health care products - Radiation: Part 2 establishing the sterilization dose | Identical |
| ISO 11137-3 Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control | IS/ISO 11137-3: 2017<br>Sterilization of Health Care Products — Radiation Part 3 Guidance on Dosimetric Aspects of Development, Validation and Routine Control | Identical |
| ISO 11607-1 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems | IS/ISO 11607: 2019<br>Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision | Identical |
| ISO 11607-2 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes | IS/ISO 11607 : 2019<br>Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision) | Identical |
| ISO 14155 Clinical investigation of medical devices for human | IS/ISO 14155 : 2020<br>Clinical investigation of medical | Identical |

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|---|---|---|
| subjects — Good clinical practice | devices for human subjects - Good clinical practice | |
| ISO 14937 Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices | IS/ISO 14937 : 2009 Sterilization of health care products General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilization process for medical devices | Identical |
| ISO 14971 Medical devices — Application of risk management to medical devices | IS/ISO 14971 : 2019 Medical devices - Application of risk management to medical devices First Revision | Identical |
| ISO 17664 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices | IS/ISO 17664 : 2017 Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices | Identical |
| ISO 17665-1 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices | IS 18319 (Part 1) : 2023 ISO 17665-1:2006 Sterilization of health care products Moist heat Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices | Identical |
| ISO 80000-1 Quantities and units — Part 1: General | IS/ISO 80000-1 : 2022 Quantities and Units Part 1 General | Identical |

The technical committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decide that they are acceptable for use in conjunction with this standard:

| *International Standard/ Other Publication* | *Title* |
|---|---|
| ISO 25424 | Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices |

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated expressing the result of a test or analysis, shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (Second Revision)’.

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**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 16061: 2021 or kindly contact:

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## SCOPE

This document specifies the general requirements for instruments to be used in association with non-active surgical implants. These requirements apply to instruments when they are manufactured and when they are supplied after refurbishment.

NOTE: In this document, unless otherwise specified, the term “instrument” refers to an instrument for use in association with non-active surgical implants.

This document also applies to instruments which can be connected to power-driven systems, but it does not apply to the power-driven systems themselves.

With regard to safety, this document gives the requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging, and information supplied by the instrument manufacturer, hereafter referred to as the manufacturer.

This document is not applicable to instruments associated with dental implants, transendodontic and transradicular implants and ophthalmic implants.