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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

गैर-सक्रिय सर्जिकल प्रत्यारोपण — सामान्य अपेक्षाएँ

(ISO 14630 : 2024, संशोधित)

Draft Indian Standard

Non-Active Surgical Implants — General Requirements

(ISO 14630 : 2024, MOD)

ICS 11.040.40

Orthopaedic Instruments, Implants and Accessories Sectional Committee, MHD 02

Last date for comments: **24 September 2025**

NATIONAL FOREWORD

(*Adoption clause will be added later*)

This standard supersedes IS 18076 : 2023 which was first published in 2023 and was identical to ISO 14630 : 2012 'Non-active surgical implants — General requirements'. This revision has been brought out to align it with the latest version of ISO 14630 : 2024.

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 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	Modified
ISO 10993-7, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	IS 17932 (Part 5):2024 IS/ISO 10993 : Part 7 : 2018 , Biological Evaluation of Medical Devices Part 5 Ethylene oxide sterilization residuals	Modified
ISO 10993-17, Biological evaluation of medical devices — Part 17: Toxicological risk assessment of medical device constituents	IS/ISO 10993-17:2002, Biological Evaluation of Medical Devices Part 17 Establishment of Allowable Limits for Leachable Substances	Identical
ISO 11135, 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, 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, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	MHD/12 (28298), Sterilization of Health Care Products — Radiation Part 1 Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices (First Revision)	Identical
ISO 11137-2, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	IS/ISO 11137-2:2013, 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, 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, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials sterile barrier systems and packaging systems	Identical

	First Revision	
ISO 11607-2, Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	IS/ISO 11607:2019, Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)	Identical
ISO 13408-1, Aseptic processing of health care products — Part 1: General requirements	MHD/12 (25954), Aseptic Processing of Health Care Products Part 1 General Requirements	Identical
ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice	IS/ISO 14155:2020, Clinical investigation of medical devices for human subjects - Good clinical practice	Identical
ISO 14160, Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	IS 18730:2024 ISO 14160:2020, Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	Identical
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 17664-1, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	IS 18742 (Part 1):2024 ISO 17664-1:2021, Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices Part 1 Critical and semi-critical medical devices	Identical
ISO 17665, Sterilization of health care products — Moist heat — Requirements for the development, validation and	IS 18319:2024 ISO 17665 : 2024, Sterilization of Health Care Products — Moist Heat — Requirements for the	Identical

routine control of a sterilization process for medical devices	Development, Validation and Routine Control of a Sterilization Process for Medical Devices (First Revision)	
ISO 22442-1, Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management	IS/ISO 22442-1:2015, Medical Devices Utilizing Animal Tissues and their Derivatives Part 1 Application of Risk Management	Identical
ISO 22442-2, Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling	IS/ISO 22442-2:2015, Medical Devices Utilizing Animal Tissues and their Derivatives Part 2 Controls on Sourcing, Collection and Handling	Identical
ISO 22442-3, Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents	IS/ISO 22442-3:2007, Medical Devices Utilizing Animal Tissues and their Derivatives Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Spongiform Encephalopathy (TSE) Agents	Identical
ISO 80000-1, Quantities and units — Part 1: General	IS/ISO 80000-1:2022, Quantities and Units Part 1 General	Identical

IS 17932 (Part 1) : 2023 is modified adoption of ISO 10993-1 : 2018 which specifies the general principles governing the biological evaluation of medical devices within a risk management process. The modification is with respect to the reference to IS/ISO 14971 : 2019.

IS 17932 (Part 5):2024 is modified adoption of ISO 10993-7 : 2008 which specifies allowable limits for residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) in individual EO-sterilized medical devices, procedures for the measurement of EO and ECH, and methods for determining compliance so that devices may be released. The modification is with respect to the reference to IS 17932 (Part 1) : 2023,as mentioned above.

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 20857	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices
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)’.

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 14630 : 2024 or kindly contact:

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SCOPE

This document specifies general requirements for non-active surgical implants, hereafter referred to as implants.

This document is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal or human tissue.

With regard to safety, this document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements.

Additional requirements applicable to specific implants or implant families are given or referred to in Level 2 and Level 3 standards.

NOTE 1 This document does not require that the manufacturer have a quality management system in place. However, many regulatory authorities require the application of a quality management system, such as that described in ISO 13485, to ensure that the implant achieves its intended performance and safety.

NOTE 2 In this document, when not otherwise specified, the term "implant" refers to each individual component of a system or a modular implant, provided separately or as a set of components, as well as to all ancillary implants or associated implants designed for improving the intended performance.