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BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

हृदयवाहिनी प्रत्यारोपण - परा-नालशलाका हृदय अवरोधक
(ISO 22679:2021)

Draft Indian Standard
Cardiovascular implants — Transcatheter cardiac occluders
(ISO 22679:2021)

[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 10555-1, Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements	IS/ISO 10555-1: 2013 Intravascular catheters - Sterile and single - Use catheters: Part 1 general requirements (First Revision)	Identical under single numbering
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 IS/ISO 10993 : Part 1 : 2009 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	Modified
ISO 10993-2, Biological evaluation of medical devices — Part 2: Animal welfare requirements	IS/ISO 10993-2 : 2006 Biological Evaluation of Medical Devices Part 2 Animal Welfare Requirements (First Revision)	Identical under single numbering
ISO 11135-1, 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 under single numbering
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	IS/ISO 11137-1 : 2006 ISO 11137-1 : 2006 Sterilization of health care products - Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices	Identical under dual numbering
ISO 11137-2, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	IS/ISO 11137-2 : 2013 ISO 11137-2 : 2013 Sterilization of health care products - Radiation: Part 2 establishing the sterilization dose	Identical under dual numbering
ISO 11137-3, Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of	IS/ISO 11137-3 : 2017 Sterilization of Health Care Products â€• Radiation Part 3 Guidance on Dosimetric	Identical under single numbering

development, validation and routine control	Aspects of Development, Validation and Routine Control	
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 (First Revision)	Identical under single numbering
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 under single numbering
ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes	IS/ISO 13485 : 2016 Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes (First Revision)	Identical under single numbering
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 under single numbering
ISO 14630, Non-active surgical implants — General requirements	IS 18076 : 2023 ISO 14630: 2012 Non-active surgical implants General requirements	Identical under dual numbering
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 under single numbering
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 under single numbering

ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	IS/ISO 15223-1 : 2016 Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision)	Identical under single numbering
ISO 15223-2, Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation	IS/ISO 15223-2 : 2010 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied: Part 2 symbol development, selection and validation	Identical under single numbering
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 under dual numbering
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 under single numbering
IEC 62366-1, Medical devices — Part 1: Application of usability engineering to medical devices	IS 17922 (Part 1) : 2023 IEC 62366-1: 2015 CSV Medical Devices Part 1: Application of Usability Engineering	Identical under dual numbering

The technical committee has reviewed the provisions of the following International Standard referred in this draft standard proposed to be adopted and has decided that it is acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
ISO 11070	Sterile single-use intravascular introducers, dilators and guidewires
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
ISO/TS 17665-2,	Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1
ISO/TS 17665-3,	Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization
ISO 20417,	Medical devices — Information to be supplied by the manufacturer
ASTM F2052,	Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
ASTM F2119,	Standard test method for evaluation of MR image artifacts from passive implants
ASTM F2182,	Standard test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging
ASTM F2213,	Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment
ASTM F2503,	Standard practice for marking medical devices and other items for safety in the magnetic resonance environment

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 important in vitro tests including functional and durability characteristics of transcatheter cardiac occluders, and their delivery systems and accessories. This document does not specify exact test methods for functional and durability testing, but it offers requirements and recommendations for performance tests of the cardiac occluder system.

Surgical occluders have been omitted from the scope of this document given their significant differences in device geometry, materials, implantation methods, and test methods as compared to transcatheter cardiac occluders.

This document is applicable to all intracardiac occluders intended for transcatheter implantation in humans (e.g. atrial septal occluder, ventricular septal occluder, patent foramen ovale occluder, left atrial appendage occluder, and paravalvular leak occluders). This document does not cover non-cardiac occluders, but elements of this document can be applicable to patent ductus arteriosus occluders.

The following devices and components are outside the scope of this document: surgical devices, cardiac shunt devices, atrial flow regulators, active components (such as sensors), or degradable or animal tissue components.

This document is applicable to both newly developed and modified cardiac occluders, their accessory devices, packaging, and labelling.

This document defines operational conditions and performance requirements for cardiac occluders where either adequate scientific or clinical evidence, or both, exists for their justification.

NOTE – At the time of this document, it is impossible to take all future and emerging technologies into consideration. The cardiac occluder systems based on these new technologies can benefit from evaluation based on the basic requirements of this document. Testing beyond the scope of this document can also be necessary in order to verify and validate these cardiac occluder 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 22679:2021or kindly contact:

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