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28 March 2024

BUREAU OF INDIAN STANDARDS

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भारतीय मानक मसौदा

हृदयवाहिनी प्रत्यारोपण एवं कृत्रिम अंग - बाह्य परिसंचरण के लिए प्रवेशनी
(ISO 18193:2021)

Draft Indian Standard
Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation
(ISO 18193:2021)

[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 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 10993-4, Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood	IS/ISO 10993-4 : 2017 Biological evaluation of medical devices Part 4 Selection of tests for interactions with blood	Identical under single numbering
ISO 10993-7, Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals	IS/ISO 10993-7 : 2018 Biological evaluation of medical devices Part 7 Ethylene oxide sterilization residuals	Identical under single numbering
ISO 10993-11, Biological evaluation of medical devices — Part 11: Tests for systemic toxicity	IS/ISO 10993-11 : 2017 Biological evaluation of medical devices Part 11 Tests for systemic toxicity	Identical under single numbering
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 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 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 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 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 80369-7, Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016 Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications	Identical under single numbering

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

International Standard	*Title*
ASTM F640-12,	Standard Test Methods For Determining Radiopacity For Medical Use
DIN 13273-7,	Catheters for medical use — Part 7: Determination of the x-ray attenuation of catheters; Requirements and testing

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

Introduction

This document is intended to ensure that cannulae designed to enable extracorporeal circulation (ECC) have been adequately tested for both their safety and function, and that cannulae characteristics are appropriately disclosed when labelling the device.

This document therefore contains procedures to be used for the evaluation of ECC cannulae. Type test procedures for determination of the cannulae performance and blood cell damage are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of cannulae that suits the needs of the patient.

This document also includes minimum reporting requirements, which allows the user to compare performance characteristics of cannulae of different designs in a standard way.

This document makes reference to other international standards in which methods for determination of characteristics common to medical devices can be found.

Requirements for animal and clinical studies have not been included in this document. Such studies can be necessary for regulatory submissions and/or be parts of a manufacturer's quality system.This document contains only those requirements that are specific to cannulae. Non-specific requirements are covered by references to other International Standards listed in Clause 2. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

Scope

This document specifies requirements for sterile, single-use cannulae for removal and delivery of patients' blood during cardiopulmonary bypass (CPB) up to 6 h duration, extracorporeal lung assist (ECLA with VV, VAV, or AV cannulation strategies), left or right heart bypass (LHB, RHB), cardiopulmonary support (CPS), extracorporeal life support (ECLS with VA cannulation strategy), extracorporeal carbon dioxide removal (ECCO2R), and other extracorporeal circulation techniques.

This standard does not apply to:

- introducers (e.g., guidewires) as addressed in ISO 11070,
- isolated organ perfusion cannulae, and
- intravascular catheters as addressed in ISO 10555-3.

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 18193:2021or kindly contact:

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