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BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

भारतीय मानक मसौदा

संवेदनाहारी और श्वसन उपकरण — वायुमार्ग और संबंधित उपकरणों के लिए सामान्य आवश्यकताएँ

[ISO 18190:2016, संशोधित]

Draft Indian Standard

Anaesthetic and respiratory equipment — General requirements for airways and related equipment

[ISO 18190:2016, MOD]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 22 August 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 Indian Standard*	*Degree of Equivalence*
ISO 7396-1, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum	MHD/11/22279/ IS 18466-1 : 2023/ ISO 7396-1 : 2016, Medical Gas Pipeline Systems Part 1 Pipeline Systems for Compressed Medical Gases and Vacuum (*First Revision*)	Identical
ISO 10524-1, Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices	IS/ISO 10524-1 : 2006, Pressure Regulators For Use with Medical Gases Part 1 Pressure Regulators and Pressure Regulators with Flow-Metering Devices	Identical
ISO 10524-3, Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves	IS/ISO 10524-3 : 2019, Pressure regulators for use with medical gases- Part 3: Pressure regulators integrated with cylinder valves VIPRs (*First Revision)*	Identical
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 (ISO 10993-1 : 2018, MOD)	Modified
ISO 11135, Sterilization of health-care products — Ethylene oxide — Requirements for 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 11137-1:2006/Amd.1:2013, Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices/Amendment 1	IS/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
ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice/Technical Corrigendum 1	IS/ISO 14155 : 2020, Clinical investigation of medical devices for human subjects - Good clinical practice	Identical

ISO 15001:2010, Anaesthetic and respiratory equipment — Compatibility with oxygen	IS/ISO 15001 : 2010, Anaesthetic and respiratory equipment - Compatibility with oxygen *(First Revision)*	Identical
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
IEC 60601-1:2005, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	MHD/15/22648/ IS 13450 (Part 1) : 2024, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1 : 2020, MOD) (*Third Revision*)	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	MHD/15/22651/ IS 13450 (Part 1/Sec 2) : 2023, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 2 Electromagnetic Disturbances — Requirements and Tests (IEC 60601-1-2 : 2020, MOD) (*Second Revision*)	Modified
IEC 60601-1-8:2006, Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	MHD/15/22654/ IS 13450 (Part 1/Sec 8) : 2023, Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance Section 8 General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems (IEC 60601-1-8 : 2020, MOD) (*First Revision*)	Modified
EN 1041, Information supplied by the manufacturer of medical devices	IS/ISO 20417 : 2021, Medical devices Information to be supplied by the manufacturer	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*
EN 556-1:2001	Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices
ASTM F640	Standard test methods for determining radiopacity for medical use
ASTM F2052	Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
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

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 shall be rounded off in accordance with IS 2: 2022 'Rules for rounding off numerical values (*revised*)'.

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

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.

The technical content of the document has not been enclosed as it is identical with the corresponding ISO standard. For details, please refer to **ISO 18190:2016** or kindly contact:

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SCOPE

This International Standard specifies the general requirements common to AIRWAYS AND RELATED EQUIPMENT and applicable to those device-specific standards that reference it.

The requirements of a device-specific standard take priority over this International Standard.

NOTE General requirements contained in this International Standard have historically been referenced in more than two other AIRWAYS AND RELATED EQUIPMENT standards.