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BUREAU OF INDIAN STANDARDS

भारतीय मानक मसौदा

चिकित्सा विद्युत उपकरण
भाग 2-67: ऑक्सीजन-संरक्षण उपकरणों की बुनियादी सुरक्षा और आवश्यक प्रदर्शन के लिए विशेष आवश्यकताएं
[ISO 80601-2-67:2020, संशोधित]

Draft Indian Standard

Medical electrical equipment
Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
[ISO 80601-2-67:2020, MOD]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD-11	Last date for comments 28 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
IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance, Clause 2 applies, except as follows:	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
ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2016/ 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
ISO 32:1977, Gas cylinders for medical use — Marking for identification of content	IS 3933 : 2021, Colour Identification of Gas Cylinders and Related Equipment Intended for Medical Use (First Revision)	Not Equivalent
ISO 5359:2014+Amd.1:2017, Low-pressure hose assemblies for use with medical gases	MHD/11/25226/ ISO 5359:2014, Anaesthetic and Respiratory Equipment Low-Pressure Hose Assemblies for Use with Medical Gases	Identical
ISO 7000, Graphical symbols for use on equipment — Registered symbols	IS 16450 : 2023/ ISO 7000:2019, Graphical Symbols for Use on Equipment — Registered Symbols (First Revision)	Identical
ISO 7396-1:2016, Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum	MHD/11/22279/ IS/ISO 7396 : Part 1: 2016, Medical Gas Pipeline Systems Part 1: Pipeline Systems for Compressed Medical Gases and Vacuum (*First Revision*)	Identical
ISO 9000:2015, Quality management systems — Fundamentals and vocabulary	IS/ISO 9000 : 2015, Quality management systems - Fundamentals and vocabulary (*Fourth Revision*)	Identical
ISO 10524-1:2018, Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices	IS 18361 (Part 1) : 2023, Pressure Regulators for use with Medical Gases : Part 1 Pressure Regulators and Pressure Regulators with Flow-Metering Devices first revision	Modified

ISO 10524-3:2019, Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (VIPRs)	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 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	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 16142-1:2016, Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	IS/ISO 16142-1 : 2016, Medical Devices - Recognized Essential Principles of Safety and Performance of Medical Devices Part 1 General Essential Principles and Additional Specific Essential Principles for all Non-IVD Medical Devices and Guidance on the Selection of Standards	Identical
ISO 17664:2017, 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 18562-1:2017, Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process	MHD/11/25205/ ISO 18562-1: 2024, Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1: Evaluation and testing within a risk management process	Modified
ISO 19223:2019, Lung ventilators and related equipment — Vocabulary and semantics	MHD/11/25366/ ISO 19223:2019, Lung ventilators and related equipment Vocabulary and semantics	Identical
ISO 80369-1:2018, Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements	IS/ISO 80369-1 : 2018, Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 1 General Requirements	Identical
ISO 80601-2-74:2017, Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of	MHD/11/25364/ ISO 80601-2-74:2021, Medical electrical equipment Part 2-74: Particular requirements for basic safety and	Modified

respiratory humidifying equipment	essential performance of respiratory humidifying equipment	
IEC 62366-1:2015, 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

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 13544-2:2002+AMD1:2009	Respiratory therapy equipment — Part 2: Tubing and connectors

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 80601-2-67:2020** or kindly contact:

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SCOPE

IEC 60601-1:2005+AMD1:2012, 1.1 is replaced by:

This document is applicable to the *basic safety* and *essential performance* of oxygen *conserving equipment*, hereafter referred to as *ME equipment,* in combination with its *accessories* intended to conserve supplemental oxygen by delivering gas intermittently and synchronized with the *patient's* inspiratory cycle, when used in the *home healthcare environment*. Oxygen *conserving equipment* is typically used by a *lay operator*.

NOTE 1 *Conserving equipment* can also be used in professional health care facilities.

This document is also applicable to *conserving equipment* that is incorporated with other equipment.

EXAMPLE

Conserving equipment combined with a pressure regulator[2], an oxygen concentrator[7] or liquid oxygen equipment[4].

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to *conserving equipment*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *conserving equipment*.

This document is intended to clarify the difference in operation of various *conserving equipment* models, as well as between the operation of *conserving equipment* and continuous flow oxygen equipment, by requiring standardized performance testing and labelling.

This document is only applicable to active devices (e.g. pneumatically or electrically powered) and is not applicable to non-active devices (e.g. reservoir cannulas).

If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.