***भारतीय मानक***

***Indian Standard***

**IS xxxxx (Part 1) : 2024**

**संवेदनाहारी और श्वसन उपकरण — मनुष्यों में श्वसन गैसों को नम करने के लिए ताप और नमी एक्सचेंजर्स (एचएमई)**

**भाग 1: 250 मिलीलीटर की न्यूनतम ज्वारीय मात्रा के साथ उपयोग के लिए एचएमई**

(ISO 9360-1:2000*,***संशोधित**)

**Anaesthetic and Respiratory Equipment — Heat and Moisture Exchangers (HMEs) for Humidifying Respired Gases in Humans**

**Part 1: HMEs for Use with Minimum Tidal Volumes of 250 ml**

(ISO 9360-1:2000, MOD)

ICS 11.040.10

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**December 2024 Price Group X**

Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11

NATIONAL FOREWORD

This Indian Standard which is modified adoption of ISO 9360-1:2000 ‘Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml’ issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and after approval of the Medical Equipment and Hospital Planning Division Council.

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:

1. Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and
2. 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 4135, Anaesthesiology — Vocabulary. | IS 13200: 2023/ ISO 4135:2022, Anaesthetic and Respiratory Equipment Vocabulary (*Second Revision)* | Identical |
| ISO 5356-1:1996, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets. | IS/ISO 5356-1: 2015, Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets *(First Revision*) | Identical |
| ISO 5356-2:1987, Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weightbearing connectors. | IS/ISO 5356-2: 2012, Anaesthetic and respiratory equipment - Conical connectors: Part 2 screw - Threaded weight - Bearing connectors | Identical |
| ISO 7000:1989, Graphical symbols for use on equipment — Index and synopsis. | IS 16450 : 2023/ ISO 7000:2019, Graphical Symbols for Use on Equipment Registered Symbols | Identical |
| ISO 11607, Packaging for terminally sterilized medical devices. | IS/ISO 11607 : 2019, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems *(First Revision)*  IS/ISO 11607 : 2019, Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision) | Identical |
| IEC 60601-1:1988, Medical electrical equipment — Part 1: General requirements for safety. | 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 |

The references Standard ISO 11607, into two parts i.e. IS/ISO 11607 : 2019 and IS/ISO 11607 : 2019

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

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*)’. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

**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.