

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY

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भारतीय मानक मसौदा
**संवेदनाहारी और श्वसन उपकरण — मनुष्यों में श्वसन गैसों को नम
करने के लिए ताप और नमी एक्सचेंजर्स (एचएमई) भाग 2: 250
मिलीलीटर की न्यूनतम ज्वारीय मात्रा वाले ट्रेकियोस्टोमाइज्ड रोगियों
के साथ उपयोग के लिए एचएमई**
[ISO 9360-2:2001, संशोधित]

Draft Indian Standard
**Anaesthetic and respiratory equipment — Heat and moisture
exchangers (HMEs) for humidifying respired gases in humans
Part 2: HMEs for use with tracheostomized patients having
minimum tidal volumes of 250 ml**
[ISO 9360-2:2001, MOD]

ICS: 11.040.10

Anaesthetic, Resuscitation and Allied
Equipment Sectional Committee, MHD-11

Last date for comments 10 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:

- Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'
- 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:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 4135, Anaesthetic and respiratory equipment — Vocabulary.	IS 13200 : 2023/ ISO 4135:2022, Anaesthetic and Respiratory Equipment Vocabulary (<i>Second Revision</i>)	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 (<i>First Revision</i>)	Identical
ISO 7000, 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 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.	MHD/11/ 25373 /, 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)	Modified
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 (<i>First Revision</i>)	
	IS/ISO 11607 : 2019, Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)	Identical

The references standard ISO 11607, to two parts i.e. IS/ISO 11607 : 2019 and IS/ISO 11607 : 2019

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 9360-2:2001** or kindly contact:

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SCOPE

This part of ISO 9360 is based on ISO 9360-1:2000 and specifies certain requirements and test methods for heat and moisture exchangers (HMEs) without machine connector ports, including those incorporating breathing system filters. These devices are intended for the humidification of respired gases for tracheostomized patients having a tidal volume of 250 ml or greater.