

NATIONAL FOREWORD

This Indian Standard which is an identical adoption of ISO 10535: 2021 ‘Assistive products — Hoists for the transfer of persons — Requirements and test methods’ issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Artificial Limbs, Rehabilitation Appliances and Equipment for the Persons with Disability Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of the 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’ appears referring to this standard, they should be read as ‘Indian Standard’; and
- b) Comma (,) has been used as a decimal marker while in Indian Standard, 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 3758 Textiles — Care labelling code using symbols	IS 14452: 2023/ISO 3758: 2012 Textiles — Care labelling code using symbols (<i>second revision</i>)	Identical
ISO 9999 Technical aids for persons with disabilities — Classification and terminology	IS 18560: 2024/ISO 9999: 2022 Assistive Products — Classification and Terminology	Identical
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing	IS 17932 (Part 1): 2023 Biological evaluation of medical devices Part 1 Evaluation and testing within a risk management process	Modified
ISO 14253-1, Geometrical Product Specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for	IS 15371 (Part 1) : 2023/ISO 14253-1:2017 Geometrical Product Specifications (GPS) — Inspection by Measurement of Workpieces and Measuring Equipment Part 1 Decision Rules	Identical

proving conformance or non-conformance with specifications	for Verifying Conformity or Nonconformity with Specifications (First Revision)	
ISO 14971 Medical devices — Application of risk management to medical devices	IS/ISO 14971: 2019 Medical devices — Application of risk management to medical devices (<i>first revision</i>)	Identical
EN 853 Rubber hoses and hose assemblies — Wire braid reinforced hydraulic type — Specification	IS 18135 : 2023/ ISO 18752 : 2022 Rubber hoses and hose assemblies — Wire or textile reinforced single pressure types for hydraulic applications — Specification	Not Equivalent
EN 854 Rubber hoses and hose assemblies — Textile reinforced hydraulic type — Specification	IS 18135 : 2023/ ISO 18752 : 2022 Rubber hoses and hose assemblies — Wire or textile reinforced single pressure types for hydraulic applications — Specification	Not Equivalent
EN 1021-1 Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: Smouldering cigarette	IS 12467 (Part 1) : 2006 Textiles — Assessment of the ignitability of upholstered furniture: Part 1 Ignition source: smouldering cigarette (first revision)	Not Equivalent
EN 1021-2, Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source: Match flame equivalent	IS 12467 (Part 2) : 2006 Textiles — Assessment of the ignitability of upholstered furniture: Part 2 Ignition source match flame equivalent (first revision)	Not Equivalent
IEC 60529 Degrees of protection provided by enclosures (IP Code)	IS/IEC 60529 : 2001 Degrees of protection provided by enclosures (IP Code)	Identical
IEC 60601-1, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance	IS 13450 (Part 1): 2024 Medical Electrical Equipment Part 1 General Requirements for Basic Safety and Essential Performance (IEC 60601-1: 2020, MOD) (<i>third revision</i>)	Modified

<p>IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety - Collateral Standard: Electromagnetic disturbances - Requirements and tests</p>	<p>IS 13450 (Part 1/Sec 2): 2024 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) (<i>second revision</i>)</p>	<p>Modified</p>
<p>IEC 61000-3-2 Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)</p>	<p>IS 14700 (Part 3/Sec 2) : 2020 IEC 61000-3-2 : 2018 Electromagnetic Compatibility (EMC) Part 3 Limits Section 2 Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (<i>third revision</i>)</p>	<p>Identical</p>
<p>IEC 61000-3-3 Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection</p>	<p>IS 14700 (Part 3/Sec 3) : 2018/IEC 61000-3-3 : 2013 Electromagnetic Compatibility (EMC) Part 3 Limits Section 3 Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply system, for equipment with rated current ≤ 16 A per phase and not subjected to conditional connection (<i>second revision</i>)</p>	<p>Identical</p>
<p>IEC 61000-4-3 Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test</p>	<p>IS 14700 (Part 4/Sec 3) : 2023/ IEC 61000-4-3 : 2020 Electromagnetic Compatibility (EMC) Part 4 Testing and Measurement Techniques Section 3 Radiated, Radio-Frequency Electromagnetic Field Immunity Test (<i>second revision</i>)</p>	<p>Identical</p>
<p>IEC 61672-1 Electroacoustics — Sound level meters — Part 1: Specifications</p>	<p>IS 15575 (Part 1): 2016/IEC 61672-1: 2013 Electroacoustics - Sound level meters: Part 1 Specifications (<i>first revision</i>)</p>	<p>Identical</p>

The Committee responsible for the preparation of this standard has reviewed the provisions of following mentioned International Standards and has decided that they are acceptable for use in conjunction with this standard:

<i>International Standard/Other Publication</i>	<i>Title</i>
ISO 3746	Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane
EN 614-1	Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles
EN 13480-3	Metallic industrial piping — Part 3: Design and calculation
EN 980	Graphical symbols for use in the labeling of medical devices
EN 12182: 1999	Technical aids for disabled persons — General requirements and test methods

In this text references have been made to international standards which have been revised as follows:

1. ISO 9999:2002, Technical aids for persons with disabilities — Classification and terminology has been revised to ISO 9999: 2022 Assistive Products — Classification and Terminology
2. IEC 60601-1: 2005: The latest version IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 CSV has been adopted as IS 13450 (Part 1): 2024 with modifications.
3. IEC 60601-1-2: 2005: The latest version IEC 60601-1-2:2014+Amd 1:2020 has been adopted as 13450 (Part 1/ Sec 2): 2024 with modifications.
4. EN 13480-3: 2017 is the latest version.

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 shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (*second revision*)’.