

BUREAU OF INDIAN STANDARDS

Program of Work

MHD 11 : Anesthetic, Resuscitation and Allied Equipment

Scope: To formulate Indian Standards for instruments and equipment used for anaesthetizing and ventilating a patient, including diagnostic instruments such as sphygmomanometers, suction apparatus and anaesthetic face mask.

Liaison: **ISO TC-121 (P): Anaesthetic and respiratory equipment** **ISO TC-121 SC-1 (P): Breathing attachments and anaesthetic machines** **ISO TC-121 SC-3 (P): Respiratory devices and related equipment used for patient care** **ISO TC-121 SC-4 (P): Vocabulary and semantics** **ISO TC-121 SC-2 (P): Airway devices and related equipment** **ISO TC-121 SC-6 (P): Medical gas supply systems** **ISO TC-121 SC-8 (P): Suction devices**

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS/ISO 10524-3 : 2019 ISO 10524-2:2019 ISO 10524-2:2019	Pressure regulators for use with medical gases- Part 3: Pressure regulators integrated with cylinder valves VIPRs First Revision		-	Identical under single numbering
2	IS/ISO 10524-4 : 2008 ISO 10524 -4 :2008 Reviewed In : 2018 ISO 10524 -4 :2008	Pressure regulators for use with medical gases: Part 4 low - Pressure regulators	December, 2018	-	Identical under single numbering
3	IS/ISO 10651-4 : 2002 ISO 10651-4 : 2002 Reviewed In : 2023 ISO 10651-4 : 2002	Lung ventilators for medical use - Particular requirements for basic safety and essential performance: Part 4 particular requirements for operator - Powered resuscitators	January, 2023	-	Identical under single numbering
4	IS/ISO 10651-5 : 2006 ISO 10651-5 : 2006 Reviewed In : 2023 ISO 10651-5 : 2006	Lung ventilators for medical use - Particular requirements for basic safety and essential performance: Part 5 gas - Powered emergency resuscitators	March, 2023	-	Identical under single numbering
5	IS/ISO 11197 : 2019 ISO 11197:2019 ISO 11197:2019	Medical Supply Units First Revision		-	Identical under single numbering
6	IS 11378 : 2002 ISO 5358 Reviewed In : 2017 ISO 5358	Anaesthetic machines for use with humans (First Revision)	March, 2017	-	Identical under dual numbering
7	IS/ISO 11712 : 2009 ISO 11712 : 2009 Reviewed In : 2019 ISO 11712 : 2009	Anaesthetic and respiratory equipment - Supralaryngeal airways and connectors	November, 2019	-	Identical under single numbering
8	IS 12417 : 1988 Reviewed In : 2019	Specification for suction apparatus, pedal operated	January, 2019	1	Indigenous

9	IS 13200 : 2023 ISO 4135:2022 ISO 4135:2022	Anaesthetic and Respiratory Equipment Vocabulary Second Revision		-	Identical under dual numbering
10	IS 13450 (Part 2/Section 12) : 2023 ISO 80601-2-12:2020 ISO 80601-2-12:2020	Medical Electrical Equipment Part 2 Particular requirements for basic safety and essential performance Section 12 Critical care ventilators (First Revision)		-	Identical under dual numbering
11	IS 13450 (Part 2/Section 13) : 2024 ISO 80601-2-13:2022	Medical Electrical Equipment: Part 2 Particular Requirements for the Basic Safety and Essential Performance: Sec 13 Anaesthetic Workstation (First Revision)		-	Modified/Technically Equivalent
12	IS 13450 (Part 2/Section 70) : 2022 ISO 80601-2-70:2020 ISO 80601-2-70:2020	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 70 : Sleep apnoea breathing therapy equipment		-	Identical under dual numbering
13	IS 13450 (Part 2/Section 79) : 2023 ISO 80601-2-79:2018 ISO 80601-2-79:2018	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 79 - Ventilatory support equipment for ventilatory impairment		-	Identical under single numbering
14	IS 13450 (Part 2/Section 80) : 2023 ISO 80601-2-80:2018 ISO 80601-2-80:2018	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 80 - Ventilatory support equipment for ventilatory insufficiency		-	Identical under single numbering
15	IS 13450 (Part 2/Section 84) : 2023 ISO 80601-2-84:2020 ISO 80601-2-84:2020	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 84 Ventilators for emergency medical services environment		-	Identical under dual numbering
16	IS/ISO 14408 : 2005 ISO 14408 : 2005 Reviewed In : 2020 ISO 14408 : 2005	Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information	April, 2020	-	Identical under single numbering
17	IS/ISO 15001 : 2010 Reviewed In : 2023 ISO 15001:2010	Anaesthetic and respiratory equipment - Compatibility with oxygen (First Revision)	January, 2023	-	Identical under single numbering
18	IS/ISO 15002 : 2008 ISO15002:2008 Reviewed In : 2023 ISO15002:2008	Flow - Metering devices for connection to terminal units of medical gas pipeline systems	January, 2023	-	Identical under single numbering
19	IS/ISO 16628 : 2008 ISO 16628 : 2008 Reviewed In : 2023 ISO 16628 : 2008	Tracheobronchial tubes - Sizing and marking	January, 2023	-	Identical under single numbering
20	IS 17426 : 2020	ICU Ventilators for use in COVID-19 - Specification		-	Indigenous
21	IS 17587 : 2021	Specification for Pedal operated resuscitator		-	Indigenous

22	IS 17625 (Part 2/Sec 69) : 2021 ISO 80601-2-69 : 2020 ISO 80601-2-69 : 2020	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 69 Oxygen Concentrator Equipment		-	Identical under dual numbering
23	IS 17812 (Part 1) : 2022 ISO 9170-1:2017 ISO 9170-1:2017	Terminal Units for Medical Gas Pipeline Systems : Part 1 Terminal Units for use with Compressed Medical Gases and Vacuum (First Revision)		-	Identical under dual numbering
24	IS 18306 : 2023	Pneumatic Tourniquet-Specification		-	Indigenous
25	IS 18360 : 2023 ISO 18082 : 2014 ISO 18082 : 2014	Anaesthetic and Respiratory Equipment Dimensions of Non-Interchangeable Screw-Threaded NIST Low-Pressure Connectors for Medical Gases		-	Identical under dual numbering
26	IS 18361 (Part 1) : 2023 ISO 10524-1 : 2018	Pressure Regulators for use with Medical Gases : Part 1 Pressure Regulators and Pressure Regulators with Flow-Metering Devices first revision		-	Modified/Technically Equivalent
27	IS 18361 (Part 2) : 2023 ISO 10524-2 : 2018 ISO 10524-2 : 2018	Pressure Regulators for use with Medical Gases Part 2 Manifold and line pressure regulators (First Revision)		-	Identical under dual numbering
28	IS 18375 (Part 1) : 2023 ISO 10079-1:2022	Medical Suction Equipment Part 1 Electrically Powered Suction Equipment		-	Modified/Technically Equivalent
29	IS 18375 (Part 2) : 2023 ISO 10079-2:2022 ISO 10079-2:2022	Medical Suction Equipment Part 2 Manually Powered Suction Equipment (Second Revision)		-	Identical under dual numbering
30	IS 18375 (Part 3) : 2023 ISO 10079-3:2022 ISO 10079-3:2022	Medical Suction Equipment Part 3 Suction Equipment Powered from a Vacuum or Positive pressure Gas Source (Second Revision)		-	Identical under dual numbering
31	IS/ISO 26782 : 2009 ISO 26782:2009 ISO 26782:2009	Anaesthetic and respiratory equipment Spirometers intended for the measurement of time forced expired volumes in humans		-	Identical under single numbering
32	IS/ISO 27427 : 2013 Reviewed In : 2021 ISO 27427:2013	Anaesthetic and Respiratory Equipment - Nebulizing Systems and Components	April, 2021	-	Identical under single numbering
33	IS 3390 : 1988 Reviewed In : 2023	Specification for sphygmomanometers, mercurial (Second Revision)	January, 2023	1	Indigenous
34	IS 3391 : 1965 Reviewed In : 2023	Specification for stethoscopes	January, 2023	-	Indigenous
35	IS 3392 : 1965 Reviewed In : 2023	Specification for anaesthetic airways	January, 2023	-	Indigenous
36	IS 3393 : 1965 Reviewed In : 2023	Specification for mouth props and airways (London Hospital Pattern)	January, 2023	-	Indigenous
37	IS 4113 : 2022 ISO 7376:2020 ISO 7376:2020	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation		-	Identical under dual numbering
38	IS 4154 : 1967	Specification for endotracheal	March, 2018	-	Indigenous

	Reviewed In : 2018	connections			
39	IS/ISO 5356-1 : 2015 Reviewed In : 2022 ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors: Part 1 cones and sockets (First Revision)	March, 2022	-	Identical under single numbering
40	IS/ISO 5356-2 : 2012 Reviewed In : 2020 ISO 5356-2:2015	Anaesthetic and respiratory equipment - Conical connectors: Part 2 screw - Threaded weight - Bearing connectors	August, 2020	-	Identical under single numbering
41	IS/ISO 5361 : 1999 ISO 5361 Reviewed In : 2022 ISO 5361	Anaesthetic and respiratory equipment - Tracheal tubes and connectors	March, 2022	-	Identical under single numbering
42	IS/ISO 5362 : 2006 ISO 5362 : 2006 Reviewed In : 2022 ISO 5362 : 2006	Anaesthetic reservoir bags	March, 2022	-	Identical under single numbering
43	IS/ISO 5364 : 2008 ISO 5364:2008 Reviewed In : 2019 ISO 5364 : 2008	Anaesthetic and respiratory equipment - Oropharyngeal airways	April, 2019	-	Identical under single numbering
44	IS/ISO 5366-1 : 2000 ISO 5366 Part 1 : 2000 Reviewed In : 2023 ISO 5366 Part 1 : 2000	Anaesthetic and respiratory equipment - Tracheostomy tubes: Part 1 tubes and connectors for use in adults	January, 2023	-	Identical under single numbering
45	IS/ISO 5367 : 2000 ISO 5367: 2000 Reviewed In : 2022 ISO 5367: 2000	Breathing tubes intended for use with anaesthetic apparatus and ventilators	March, 2022	-	Identical under single numbering
46	IS 5622 : 1970 Reviewed In : 2021	Soda-Lime Canisters for Use with Gas Anaesthetic Apparatus (Waters' to-and-Fro)	February, 2021	-	Indigenous
47	IS 5680 : 1969 Reviewed In : 2020	Specification for rubber tubing for medical use	January, 2020	1	Indigenous
48	IS 6190 : 1971 Reviewed In : 2019	Specification for anaesthetic face masks	January, 2019	1	Indigenous
49	IS 6194 : 1971 Reviewed In : 2021	Specification for intermittent positive pressure respirator, bag type, manually operated	February, 2021	-	Indigenous
50	IS 6207 : 1971 Reviewed In : 2023	Specification for trolleys for oxygen cylinders	January, 2023	-	Indigenous
51	IS 6581 : 1972 Reviewed In : 2018	Specification for endotracheal tubes (Rubber)	March, 2018	1	Indigenous
52	IS 6807 : 1972 Reviewed In : 2018	Reinforced (Flexo-metallic) Magill's Endotracheal Tube	March, 2018	-	Indigenous
53	IS 7176 : 1985 Reviewed In : 2021	Specification for anaesthetic apparatus, drawover portable type (First Revision)	April, 2021	-	Indigenous
54	IS/ISO 7396-1 : 2007 Reviewed In : 2019	Medical gas pipeline systems: Part 1 pipeline systems for compressed medical gases and vacuum	June, 2019	3	Indigenous
55	IS/ISO 7396-2 : 2007 Reviewed In : 2019	Medical gas pipelines systems: Part 2 gas scavenging disposal systems	June, 2019	-	Indigenous
56	IS 7625 : 1975	Gag, Mouth, Doyen's Pattern	January, 2023	1	Indigenous

	Reviewed In : 2023				
57	IS 7652 : 1988 Reviewed In : 2021	Specification for sphygmomanometer, aneroid type (First Revision)	February, 2021	-	Indigenous
58	IS 7885 : 1985 Reviewed In : 2023	Spray, Macintosh's Pattern	January, 2023	-	Indigenous
59	IS/IEC 80601-2-30) : 2018 IEC80601-2-30 : 2018 IEC 80601-2-30:2018	Medical electrical equipment: Part 2 - 30 particular requirements for basic safety and essential performance of automated non - Invasive sphygmomanometers		-	Identical under single numbering
60	IS/ISO 81060-1 : 2007 IEC81060_1 : 2007 Reviewed In : 2023 IEC81060_1 : 2007	Non - Invasive sphygmomanometers: Part 1 requirements and test methods for non - Automated measurement type	January, 2023	-	Identical under single numbering
61	IS/ISO 81060-2 : 2018 ISO 81060-2:2018 ISO 81060-2:2018	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type		-	Identical under single numbering
62	IS 8254 (Part 1) : 1976 Reviewed In : 2023	Valve, Non-Rebreathing - Part I : Ruben's Pattern	January, 2023	-	Indigenous
63	IS 8254 (Part 2) : 1976 Reviewed In : 2023	Value, Non-rebreathing - Part II : Ambu-hesse's Pattern	January, 2023	-	Indigenous
64	IS 8312 : 1977 Reviewed In : 2019	Forceps, Introducing, Endotracheal Tube, Magill's Pattern	January, 2019	1	Indigenous
65	IS 8432 : 1977 Reviewed In : 2019	Specification for tubes, tracheostomy (Rubber Or Plastics)	April, 2019	1	Indigenous
66	IS/ISO 9170-2 : 2008 ISO 9170 : Part 2 :2008 Reviewed In : 2022 ISO 9170-2 :2008	Terminal units for medical gas pipeline systems: Part 2 terminal units for anaesthetic gas scavenging systems	March, 2022	-	Identical under single numbering
67	IS 9462 : 1980 Reviewed In : 2023	Specification for humidifier, nebulizing, ventury type	January, 2023	-	Indigenous

Standards under Development

Projects Approved

SI. No.	Doc No.	Title
1	MHD 11 (25367)	Systems for evacuation of plume generated by medical devices
2	MHD 11 (25368)	Anaesthetic vaporizers Agent specific filling systems
3	MHD 11 (25369)	Gas mixers for medical use Stand-alone gas mixers
4	MHD 11 (25370)	Inhalational anaesthesia systems Draw-over anaesthetic systems
5	MHD 11 (25375)	Anaesthetic and respiratory equipment General requirements for airways and related equipment
6	MHD 11 (25376)	Anaesthetic and respiratory equipment Voice prostheses
7	MHD 11 (25384)	Anaesthetic and respiratory equipment Cuff pressure indication control and regulation devices
8	MHD 11 (25388)	Anaesthetic and respiratory equipment Air entrainment devices
9	MHD 11 (25389)	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 3 Tests for emissions of volatile organic substances
10	MHD 11 (25390)	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 4 Tests for leachables in condensate
11	MHD 11 (25392)	Respiratory equipment Particular requirements for basic safety and essential performance of

		infant cardiorespiratory monitors
12	MHD 11 (25393)	Respiratory equipment Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors
13	MHD 11 (25396)	Anaesthetic and respiratory equipment Passive humidifiers
14	MHD 11 (25397)	Guidance on the selection of the appropriate means of ventilation based on the intended patient use environment and operator
15	MHD 11 (25398)	Anaesthetic and respiratory equipment Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans
16	MHD 11 (25399)	Anaesthetic and respiratory equipment Spirometers intended for the measurement of time forced expired volumes in humans

Preliminary Draft Standards

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Drafts Standards in WC Stage

SI. No.	Doc No.	Title
1	MHD 11 (25365)	Medical electrical equipment Part 2-67 Particular requirements for basic safety and essential performance of oxygen-conserving equipment
2	MHD 11 (25366)	Lung ventilators and related equipment Vocabulary and semantics
3	MHD 11 (25371)	Anaesthetic and respiratory equipment User-applied labels for syringes containing drugs used during anaesthesia Colours design and performance
4	MHD 11 (25372)	Medical electrical equipment Part 2-55 Particular requirements for the basic safety and essential performance of respiratory gas monitors
5	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
6	MHD 11 (25374)	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
7	MHD 11 (25381)	Breathing system filters for anaesthetic and respiratory use Part 1 Salt test method to assess filtration performance
8	MHD 11 (25383)	Breathing system filters for anaesthetic and respiratory use Part 2 Non-filtration aspects
9	MHD 11 (25387)	Medical electrical equipment Deployment implementation and operational guidelines for identifying febrile humans using a screening thermograph

Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
1	MHD 11 (25362)	Medical electrical equipment Part 2-90 Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment
2	MHD 11 (25363)	Medical electrical equipment Part 2-72 Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
3	MHD 11 (25364)	Medical electrical equipment Part 2-74 Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Finalized Draft Indian Standard

SI. No.	Doc No.	Title
1	MHD 11 (25299) Revision of: IS/ISO 11712:2009	Anaesthetic and respiratory equipment Supralaryngeal airways and connectors First Revision

Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
1	MHD 11 (18949) Revision of: IS 3393:1965	Mouth Props and Airways London Hospital Pattern Specification First Revision

2	MHD 11 (18974) Revision of: IS 8254:1976	Valve Non-Rebreathing Specification Part 1 Ruben s Pattern First Revision
3	MHD 11 (18975) Revision of: IS 8254:1976	Specification for Valve Non-Rebreathing Part 2 Ambu-Hesses Pattern First Revision
4	MHD 11 (19247) Revision of: IS 7176:1985	Drawover Portable Type Anaesthetic Apparatus - Specification Second Revision
5	MHD 11 (22279) Revision of: IS/ISO 7396:2007	Medical Gas Pipeline Systems Part 1 Pipeline Systems for Compressed Medical Gases and Vacuum First Revision
6	MHD 11 (22425)	Anaesthetic and Respiratory Equipment Tracheostomy Tubes and Connectors
7	MHD 11 (22610) Revision of: IS/ISO 10651:2002	Lung Ventilators Part 4 Particular Requirements for User Powered Resuscitators First Revision
8	MHD 11 (22611) Revision of: IS/ISO 16628:2008	Anaesthetic and Respiratory Equipment-Tracheobronchial tubes First Revision
9	MHD 11 (22613) Revision of: IS/ISO 5367:2000	Anaesthetic and Respiratory Equipment-Breathing Sets and Connectors
10	MHD 11 (22615) Revision of: IS/ISO 5364:2008	Anaesthetic and Respiratory Equipment- Oropharyngeal Airways First Revision
11	MHD 11 (22626)	Suction Catheters for Use in the Respiratory Tract
12	MHD 11 (24987) Revision of: IS/ISO 5361:1999	Anaesthetic and respiratory equipment Tracheal tubes and connectors First Revision
13	MHD 11 (25205)	Biocompatibility evaluation of breathing gas pathways in healthcare applications Part 1 Evaluation and testing within a risk management process
14	MHD 11 (25208)	Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications Part 2 Tests for Emissions of Particulate Matter
15	MHD 11 (25224)	Medical Devices Sleep Apnoea Breathing Therapy Masks and Application Accessories
16	MHD 11 (25225)	Anaesthetic and Respiratory Equipment Low-Flow Nasal Cannulae for Oxygen Therapy
17	MHD 11 (25226)	Anaesthetic and Respiratory Equipment Low-Pressure Hose Assemblies for Use with Medical Gases
18	MHD 11 (25228)	Medical Suction Equipment Part 4 General Requirements
19	MHD 11 (25230)	Medical electrical equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 87 High Frequency Ventilators

Total Published Standards:62 Total Standards Under development:48

Aspect Wise Report

Product : 60
Code of Practices : 3
Methods of Test : 2
Terminology : 1
Dimensions : 1
System Standard : 0
Safety Standard : 0
Others : 0
Service Specification : 0
Process Specification : 0
Unclassified : 0

Annexure-I :List of Indian Standards Withdrawn/Superseded

SI. No.	IS No. & Year	Title
1	IS/ISO 10079-2 : 2014 ISO 10079-2: 2014 Reviewed In : 2023 ISO 10079-2: 2014	Medical Suction Equipment Part 2 Manually Powered Suction Equipment First Revision
2	IS/ISO 10079-3 : 2014 ISO 10079-3 : 2014 Reviewed In : 2023 ISO 10079-3 :2014	Medical suction equipment Part 3 suction equipment powered from a vacuum or positive pressure gas source First Revision

3	IS/ISO 10524-1 : 2006 ISO 10524-1:2006 Reviewed In : 2023 ISO 10524-1:2006	Pressure Regulators For Use with Medical Gases Part 1 Pressure Regulators and Pressure Regulators with Flow-Metering Devices
4	IS/ISO 10524-2 : 2005 ISO10524-2:2005 Reviewed In : 2023 ISO10524-2:2005	Pressure Regulators for use with Medical Gases Part 2 Manifold and Line Pressure Regulators
5	IS/ISO 10651-3 : 1997 ISO 10651-3 : 1997 Reviewed In : 2023 ISO 10651-3 : 1997	Lung ventilators for medical use Part 3 particular requirements for emergency and transport ventilators
6	IS/ISO 10651-6 : 2004 ISO 10651-6 : 2004 Reviewed In : 2023 ISO 10651-6 : 2004	Lung ventilators for medical use - Particular requirements for basic safety and essential performance Part 6 home - Care ventilatory support devices
7	IS 11363 : 1985 ISO 5367 Reviewed In : 2011	Tubes breathing for anaesthetic apparatus and ventilators
8	IS 11364 : 1994 ISO 5362 Reviewed In : 2010	Anaesthetic Reservoir Bags
9	IS 11807 : 1994 ISO 5364 Reviewed In : 2010	Oropharyngeal Airways
10	IS 11808 : 1986 ISO 7228 Reviewed In : 2011	Tracheal Tubes Connectors
11	IS 12504 (Part 1) : 1988 ISO 5361-1 Reviewed In : 2009	Tracheal Tubes - Part 1 General Requirements
12	IS 12504 (Part 2) : 1988 ISO 5361-2 Reviewed In : 2010	Tracheal Tubes - Part 2 Oro-tracheal and Naso-tracheal Tubes of the Magill Type Plain and Cuffed
13	IS 12504 (Part 4) : 1988 Reviewed In : 2004	Specification for Tracheal Tubes - Part 4 Cole Type
14	IS 12505 (Part 1) : 1988 ISO 5366-1 Reviewed In : 2010	Tracheostomy Tubes Part 1 Connectors
15	IS 12505 (Part 2) : 1988 ISO 5366-2 Reviewed In : 2010	Tracheostomy Tubes Part 2 Basic Requirements
16	IS 4113 (Part 1) : 2003 ISO 7376 : Part 1 Reviewed In : 2023 ISO 7376 : Part 1	Laryngoscopic fittings Part 1 conventional hook - On type handle - Blade fittings Second Revision
17	IS 4113 (Part 2) : 2003 ISO 7376 : Part 2 Reviewed In : 2023 ISO 7376 : Part 2	Laryngoscopic fittings Part 2 miniature electric lamps - Screw threads and sockets for conventional blades Second Revision
18	IS 4533 : 1995 Reviewed In : 2021	Suction apparatus - Specification Second Revision
19	IS 5602 : 1970 Reviewed In : 2009	Specification for Anaesthetic Breathing Bags
20	IS 7409 (Part 1) : 2003 ISO 5356-1 Reviewed In : 2009	Anaesthetic and Respiratory Equipment - Conical Connectors - Part 1 Cones and Sockets
21	IS 7409 (Part 2) : 1994 ISO 5356-2	Anaesthetic and respiratory equipment - Conical connectors Part 2 screw - Threaded weight - Bearing connectors Second Revision

	Reviewed In : 2021 ISO 5356-2	
22	IS/ISO 80601-2-13 : 2011 ISO 80601-2-13 : 2011 Reviewed In : 2023 ISO 80601-2-13_2011	Medical electrical equipment Part 2 particular requirements for the basic safety and essential performance Sec 13 anaesthetic workstation
23	IS/ISO 80601-2-12 : 2011 80601-2-12 : 2011 Reviewed In : 2023 ISO 80601-2-12:2011	Medical electrical equipment Part 2 - 12 particular requirements for basic safety and essential performance of critical care ventilators
24	IS 8382 : 1977 Reviewed In : 2011	Pressure Regulators Pre-set Used with Medical Gas Cylinders
25	IS/ISO 9170-1 : 2008 Reviewed In : 2021 ISO 9170-1:2008	Terminal units for medical gas pipeline systems Part 1 terminal units for use with compressed medical gases and vacuum

Annexure-II :List of Indian Product Standards

SI. No.	IS No. & Year	Title
1	IS/ISO 10524-3 : 2019 ISO 10524-2:2019 ISO 26262-2:2018	Pressure regulators for use with medical gases- Part 3 Pressure regulators integrated with cylinder valves VIPRs First Revision
2	IS/ISO 10524-4 : 2008 ISO 10524 -4 :2008 Reviewed In : 2018 ISO 10524 -4 :2008	Pressure regulators for use with medical gases Part 4 low - Pressure regulators
3	IS/ISO 10651-4 : 2002 ISO 10651-4 : 2002 Reviewed In : 2023 ISO 10651-4 : 2002	Lung ventilators for medical use - Particular requirements for basic safety and essential performance Part 4 particular requirements for operator - Powered resuscitators
4	IS/ISO 10651-5 : 2006 ISO 10651-5 : 2006 Reviewed In : 2023 ISO 10651-5 : 2006	Lung ventilators for medical use - Particular requirements for basic safety and essential performance Part 5 gas - Powered emergency resuscitators
5	IS/ISO 11197 : 2019 ISO 11197:2019 ISO 16304:2018	Medical Supply Units First Revision
6	IS 11378 : 2002 ISO 5358 Reviewed In : 2017 ISO 5358	Anaesthetic machines for use with humans First Revision
7	IS/ISO 11712 : 2009 ISO 11712 : 2009 Reviewed In : 2019 ISO 11712 : 2009	Anaesthetic and respiratory equipment - Supralaryngeal airways and connectors
8	IS 12417 : 1988 Reviewed In : 2019	Specification for suction apparatus pedal operated
9	IS 13450 (Part 2/Sec 12) : 2023 ISO 80601-2-12:2020	Medical Electrical Equipment Part 2 Particular requirements for basic safety and essential performance Section 12 Critical care ventilators First Revision
10	IS 13450 (Part 2/Sec 13) : 2024	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Sec 13 Anaesthetic Workstation First Revision
11	IS 13450 (Part 2/Sec 70) : 2022 ISO 80601-2-70:2020 ISO 8000-62 : 2022	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 70 Sleep apnoea breathing therapy equipment
12	IS 13450 (Part 2/Sec 79) :	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential

	2023 ISO 80601-2-79:2018	performance Section 79 - Ventilatory support equipment for ventilatory impairment
13	IS 13450 (Part 2/Sec 80) : 2023 ISO 80601-2-80:2018	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 80 - Ventilatory support equipment for ventilatory insufficiency
14	IS 13450 (Part 2/Sec 84) : 2023 ISO 80601-2-84:2020	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential performance Section 84 Ventilators for emergency medical services environment
15	IS/ISO 15002 : 2008 ISO15002:2008 Reviewed In : 2023 ISO15002:2008	Flow - Metering devices for connection to terminal units of medical gas pipeline systems
16	IS/ISO 16628 : 2008 ISO 16628 : 2008 Reviewed In : 2023 ISO 16628 : 2008	Tracheobronchial tubes - Sizing and marking
17	IS 17426 : 2020	ICU Ventilators for use in COVID-19 - Specification
18	IS 17587 : 2021 IWA 31	Specification for Pedal operated resuscitator
19	IS 17625 (Part 2/Sec 69) : 2021 ISO 80601-2-69 : 2020 ISO/TR 19601 : 2017	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Section 69 Oxygen Concentrator Equipment
20	IS 17812 (Part 1) : 2022 ISO 9170-1:2017 ISO 17665-1:2006	Terminal Units for Medical Gas Pipeline Systems Part 1 Terminal Units for use with Compressed Medical Gases and Vacuum First Revision
21	IS 18306 : 2023	Pneumatic Tourniquet- Specification
22	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
23	IS 18361 (Part 2) : 2023 ISO 10524-2 : 2018	Pressure Regulators for use with Medical Gases Part 2 Manifold and line pressure regulators First Revision
24	IS 18375 (Part 1) : 2023	Medical Suction Equipment Part 1 Electrically Powered Suction Equipment
25	IS 18375 (Part 2) : 2023 ISO 10079-2:2022	Medical Suction Equipment Part 2 Manually Powered Suction Equipment Second Revision
26	IS 18375 (Part 3) : 2023 ISO 10079-3:2022	Medical Suction Equipment Part 3 Suction Equipment Powered from a Vacuum or Positive pressure Gas Source Second Revision
27	IS/ISO 26782 : 2009 ISO 26782:2009	Anaesthetic and respiratory equipment Spirometers intended for the measurement of time forced expired volumes in humans
28	IS/ISO 27427 : 2013 Reviewed In : 2021 ISO 27427:2013	Anaesthetic and Respiratory Equipment - Nebulizing Systems and Components
29	IS 3390 : 1988 Reviewed In : 2023	Specification for sphygmomanometers mercurial Second Revision
30	IS 3391 : 1965 Reviewed In : 2023	Specification for stethoscopes
31	IS 3392 : 1965 Reviewed In : 2023	Specification for anaesthetic airways

32	IS 3393 : 1965 Reviewed In : 2023	Specification for mouth props and airways London Hospital Pattern
33	IS 4113 : 2022 ISO 7376:2020	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation
34	IS 4154 : 1967 Reviewed In : 2018	Specification for endotracheal connections
35	IS/ISO 5356-1 : 2015 ISO 5356-1 : 2015 Reviewed In : 2022 ISO 5356-1:2015	Anaesthetic and respiratory equipment - Conical connectors Part 1 cones and sockets First Revision
36	IS/ISO 5356-2 : 2012 Reviewed In : 2020 ISO 5356-2:2015	Anaesthetic and respiratory equipment - Conical connectors Part 2 screw - Threaded weight - Bearing connectors
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