### **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 anaesthesing 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:	Pressure regulators for use with		-	Identical under single
	2019	medical gases- Part 3: Pressure			numbering
	ISO 10524-2:2019	regulators integrated with cylinder			
	ISO 10524-2:2019	valves VIPRs First Revision			
2	IS/ISO 10524-4:	Pressure regulators for use with	December, 2018	-	Identical under single
	2008	medical gases: Part 4 low -			numbering
	ISO 10524 -4 :2008	Pressure regulators			
	Reviewed In: 2018				
	ISO 10524 -4 :2008				
3	IS/ISO 10651-4:	Lung ventilators for medical use -	January, 2023	-	Identical under single
	2002	Particular requirements for basic			numbering
	ISO 10651-4 : 2002	safety and essential performance:			
	Reviewed In: 2023	Part 4 particular requirements for			
	ISO 10651-4:2002	operator - Powered resuscitators			
4	IS/ISO 10651-5:	Lung ventilators for medical use -	March, 2023	-	Identical under single
	2006	Particular requirements for basic			numbering
	ISO 10651-5 : 2006	safety and essential performance:			
	Reviewed In: 2023	Part 5 gas - Powered emergency			
	ISO 10651-5 : 2006	resuscitators			
5	IS/ISO 11197 : 2019	11 5		-	Identical under single
	ISO 11197:2019	Revision			numbering
	ISO 11197:2019				
6	IS 11378 : 2002	Anaesthetic machines for use with	March, 2017	-	Identical under dual
	ISO 5358	humans (First Revision)			numbering
	Reviewed In: 2017				
	ISO 5358				
7	IS/ISO 11712 : 2009	1 2	November, 2019	-	Identical under single
	ISO 11712 : 2009	equipment - Supralaryngeal			numbering
	Reviewed In: 2019	airways and connectors			
	ISO 11712 : 2009				
8		Specification for suction apparatus,	January, 2019	1	Indigenous
	Reviewed In: 2019	pedal operated			

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9	IS 13200 : 2023	Anaesthetic and Respiratory		-	Identical under dual
	ISO 4135:2022	Equipment Vocabulary Second			numbering
	ISO 4135:2022	Revision			
10	*	Medical Electrical Equipment Part		-	Identical under dual
		2 Particular requirements for basic			numbering
	ISO	safety and essential performance			
	80601-2-12:2020	Section 12 Critical care ventilators			
	ISO	(First Revision)			
	80601-2-12:2020				
11	IS 13450 (Part 2/Sec	Medical Electrical Equipment: Part		-	Modified/Technically
	13): 2024	2 Particular Requirements for the			Equivalent
	ISO	Basic Safety and Essential			
	80601-2-13:2022	Performance: Sec 13 Anaesthetic			
		Workstation (First Revision)			
12	IS 13450 (Part 2/Sec	Medical electrical equipment Part		-	Identical under dual
	70): 2022	2 - Particular requirements for			numbering
	ISO	basic safety and essential			
	80601-2-70:2020	performance Section 70 : Sleep			
	ISO	apnoea breathing therapy			
	80601-2-70:2020	equipment			
13	IS 13450 (Part 2/Sec	Medical electrical equipment Part		-	Identical under single
	79): 2023	2 - Particular requirements for			numbering
	ISO	basic safety and essential			
	80601-2-79:2018	performance Section 79 -			
	ISO	Ventilatory support equipment for			
	80601-2-79:2018	ventilatory impairment			
14		Medical electrical equipment Part		-	Identical under single
	80) : 2023	2 - Particular requirements for			numbering
	ISO	basic safety and essential			
	80601-2-80:2018	performance Section 80 -			
	ISO	Ventilatory support equipment for			
	80601-2-80:2018	ventilatory insufficiency			
15		Medical electrical equipment Part		<u> </u>	Identical under dual
13	84): 2023	2 - Particular requirements for			numbering
	ISO	basic safety and essential			numoering
	80601-2-84:2020	performance Section 84 Ventilators			
	ISO	for emergency medical services			
	80601-2-84:2020	environment			
16	IS/ISO 14408 : 2005	Tracheal tubes designed for laser	April, 2020	<u> </u>	Identical under single
10	ISO 14408 : 2005	surgery - Requirements for	1 spin, 2020		numbering
	Reviewed In : 2020	marking and accompanying			numbering
	ISO 14408 : 2005	information			
17	IS/ISO 15001 : 2010		January, 2023	<del> </del> -	Identical under single
' '	15/150 15001 . 2010	equipment - Compatibility with	January, 2023	_	numbering
	Reviewed In: 2023	oxygen (First Revision)			numbering
	ISO 15001:2010	oxygen (first kevision)			
18	IS/ISO 15001:2010 IS/ISO 15002 : 2008	Flow Materina devices for	January 2022	+	Identical under single
10	ISO15002:2008	Flow - Metering devices for connection to terminal units of	January, 2023	_	Identical under single
	Reviewed In : 2023				numbering
		medical gas pipeline systems			
10	ISO15002:2008	Trachachronobiol tubes Cining	January 2022	+	Identical under single
19	IS/ISO 16628 : 2008	Tracheobronchial tubes - Sizing	January, 2023	_	Identical under single
	ISO 16628 : 2008	and marking			numbering
	Reviewed In : 2023				
20	ISO 16628 : 2008	ICH Vandilata and C			T
20	IS 17426 : 2020	ICU Ventilators for use in		-	Indigenous
		COVID-19 - Specification			
<u> </u>	IC 18508 2021			1	T 11
21	IS 17587 : 2021	Specification for Pedal operated		-	Indigenous
		resuscitator		1	
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22	•	Medical Electrical Equipment Part		-	Identical under dual
	69): 2021	2 Particular Requirements for			numbering
	ISO 80601-2-69 :	Basic Safety and Essential			
	2020	Performance Section 69 Oxygen			
	ISO 80601-2-69:	Concentrator Equipment			
	2020				
23	IS 17812 (Part 1):	Terminal Units for Medical Gas		-	Identical under dual
	2022	Pipeline Systems : Part 1 Terminal			numbering
	ISO 9170-1:2017	Units for use with Compressed			
	ISO 9170-1:2017	Medical Gases and Vacuum (First			
		Revision)			
24	IS 18306 : 2023	Pneumatic Tourniquet-		-	Indigenous
		Specification			
25	IS 18360 : 2023	Anaesthetic and Respiratory		-	Identical under dual
	ISO 18082 : 2014	Equipment Dimensions of Non-			numbering
	ISO 18082 : 2014	Interchangeable Screw-Threaded			indinio ¢1 mg
	150 10002 . 201 .	NIST Low-Pressure Connectors for			
		Medical Gases			
26	IS 18361 (Part 1):	Pressure Regulators for use with			Modified/Technically
20	2023	Medical Gases : Part 1 Pressure		_	•
					Equivalent
	180 10524-1 : 2018	Regulators and Pressure Regulators			
		with Flow-Metering Devices first			
		revision			
27	IS 18361 (Part 2):	Pressure Regulators for use with		-	Identical under dual
		Medical Gases Part 2 Manifold and			numbering
	ISO 10524-2 : 2018	line pressure regulators (First			
	ISO 10524-2 : 2018	Revision)			
28	IS 18375 (Part 1):	Medical Suction Equipment Part 1		-	Modified/Technically
	2023	Electrically Powered Suction			Equivalent
	ISO 10079-1:2022	Equipment			
29	IS 18375 (Part 2):	Medical Suction Equipment Part 2		-	Identical under dual
	2023	Manually Powered Suction			numbering
	ISO 10079-2:2022	Equipment (Second Revision)			
	ISO 10079-2:2022				
30		Medical Suction Equipment Part 3		-	Identical under dual
	2023	Suction Equipment Powered from			numbering
	ISO 10079-3:2022	a Vacuum or Positive pressure Gas			
	ISO 10079-3:2022	Source (Second Revision)			
31	IS/ISO 26782 : 2009			<del> </del>	Identical under single
	ISO 26782:2009	equipment Spirometers intended			numbering
	ISO 26782:2009	for the measurement of time			numbering
	130 20782.2009				
32	IS/ISO 27427 : 2013	forced expired volumes in humans	April, 2021		Identical under single
32	13/130 2/42/: 2013	· · ·	Aprii, 2021	-	Identical under single
	Davis II 0001	Equipment - Nebulizing Systems			numbering
	Reviewed In : 2021	and Components			
	ISO 27427:2013			<u>.</u>	
33	IS 3390 : 1988	Specification for	January, 2023	1	Indigenous
	Reviewed In: 2023	sphygmomanometers, mercurial			
		(Second Revision)			
34	IS 3391 : 1965	Specification for stethoscopes	January, 2023	-	Indigenous
	Reviewed In: 2023				
35	IS 3392 : 1965	Specification for anaesthetic	January, 2023	-	Indigenous
L	Reviewed In: 2023	airways			
36	IS 3393 : 1965	Specification for mouth props and	January, 2023	-	Indigenous
	Reviewed In: 2023	airways (London Hospital Pattern)	-		
37	IS 4113 : 2022	Anaesthetic and respiratory		-	Identical under dual
	ISO 7376:2020	equipment - Laryngoscopes for			numbering
	ISO 7376:2020	tracheal intubation			
38	IS 4154 : 1967	Specification for endotracheal	March, 2018	-	Indigenous
	I	1 1	,	I	

	Reviewed In: 2018	connections		1	1
39	IS/ISO 5356-1:	Anaesthetic and respiratory	March, 2022	-	Identical under single
	2015	equipment - Conical connectors:			numbering
	ISO 5356-1 : 2015	Part 1 cones and sockets (First			
	Reviewed In: 2022	Revision)			
	ISO 5356-1:2015				
40	IS/ISO 5356-2:	Anaesthetic and respiratory	August, 2020	-	Identical under single
	2012	equipment - Conical connectors:			numbering
	Reviewed In: 2020	Part 2 screw - Threaded weight -			
	ISO 5356-2:2015	Bearing connectors			
41	IS/ISO 5361 : 1999	Anaesthetic and respiratory	March, 2022	-	Identical under single
	ISO 5361	equipment - Tracheal tubes and			numbering
	Reviewed In: 2022	connectors			
	ISO 5361				
42	IS/ISO 5362 : 2006	Anaesthetic reservoir bags	March, 2022	-	Identical under single
	ISO 5362 : 2006				numbering
	Reviewed In: 2022				
	ISO 5362 : 2006				
43	IS/ISO 5364 : 2008	Anaesthetic and respiratory	April, 2019	-	Identical under single
	ISO 5364:2008	equipment - Oropharyngeal			numbering
	Reviewed In: 2019	airways			
	ISO 5364 : 2008				
44	IS/ISO 5366-1:	Anaesthetic and respiratory	January, 2023	-	Identical under single
	2000	equipment - Tracheostomy tubes:			numbering
	ISO 5366 Part 1:	Part 1 tubes and connectors for use			
	2000	in adults			
	Reviewed In: 2023				
	ISO 5366 Part 1:				
	2000				
45	IS/ISO 5367 : 2000	Breathing tubes intended for use	March, 2022	-	Identical under single
	ISO 5367: 2000	with anaesthetic apparatus and			numbering
	Reviewed In: 2022	ventilators			
1.5	ISO 5367: 2000		T.1 2021		· · ·
46	IS 5622 : 1970	Soda-Lime Canisters for Use with	February, 2021	-	Indigenous
	Reviewed In: 2021	Gas Anaesthetic Apparatus (			
47	IC 5000 1000	Waters' to-and-Fro)	I 2020	1	To dia anana
47	IS 5680 : 1969 Reviewed In : 2020	Specification for rubber tubing for medical use	January, 2020	1	Indigenous
48	IS 6190 : 1971	Specification for anaesthetic face	January, 2019	1	Indigenous
46	Reviewed In : 2019	masks	January, 2019	1	indigenous
49	IS 6194 : 1971	Specification for intermittent	February, 2021		Indigenous
49	Reviewed In : 2021		reditionly, 2021	-	margenous
	Kevieweu III: 2021	positive pressure respirator, bag type, manually operated			
50	IS 6207 : 1971	Specification for trolleys for	January, 2023	_	Indigenous
	Reviewed In : 2023	oxygen cylinders	January, 2023		murgenous
51	IS 6581 : 1972	Specification for endotracheal	March, 2018	1	Indigenous
	Reviewed In : 2018	tubes (Rubber)	17141011, 2010		muigenous
52	IS 6807 : 1972	Reinforced (Flexo-metallic)	March, 2018	_	Indigenous
	Reviewed In : 2018	Magill's Endotracheal Tube	1,141011, 2010		marganous
53	IS 7176 : 1985	Specification for anaesthetic	April, 2021	_	Indigenous
	Reviewed In : 2021	apparatus, drawover portable type	. ipiii, 2021		marganous
	110 110 110 111 1 2021	(First Revision)			
54	IS/ISO 7396-1:	Medical gas pipeline systems: Part	June, 2019	3	Indigenous
	2007	1 pipeline systems for compressed			
	Reviewed In: 2019	medical gases and vacuum			
55	IS/ISO 7396-2 :	Medcal gas pipelines systems: Part	June, 2019	_	Indigenous
	2007	2 gas scavenging disposal systems			
	Reviewed In: 2019				
56	IS 7625 : 1975	Gag, Mouth, Doyen's Pattern	January, 2023	1	Indigenous
1		1	<b>3</b> /	1	I

ı	In 11. 2022	1		1	I
	Reviewed In: 2023 IS 7652: 1988	Caraifiantian fan	F-1 2021		To dia anno
57		Specification for	February, 2021	-	Indigenous
	Reviewed In: 2021	sphygmomanometer, aneroid type			
58	10 7005 1005	(First Revision)	I 2022		To dia anno
38	IS 7885 : 1985	Spray, Macintosh's Pattern	January, 2023	-	Indigenous
59	Reviewed In: 2023 IS/IEC 80601-2-30)	Madiant state of a second Day			The deal and a single
39	/	Medical electrical equipment: Part		-	Identical under single
	: 2018 IEC80601-2-30 :	2 - 30 particular requirements for			numbering
		basic safety and essential			
	2018 IEC	performance of automated non -			
		Invasive sphygmomanometers			
	80601-2-30:2018	Non - Invasive	1 2022		T1 (1 1 1 1 1
60	IS/ISO 81060-1 : 2007		January, 2023	-	Identical under single
		sphygmomanometers: Part 1			numbering
	IEC81060_1 : 2007	requirements and test methods for			
	Reviewed In : 2023	non - Automated measurement			
(1	IEC81060_1:2007	type			The deal on the deal
61	IS/ISO 81060-2:	Non-invasive sphygmomanometers		-	Identical under single
	2018	- Part 2: Clinical investigation of			numbering
	ISO 81060-2:2018	intermittent automated			
	ISO 81060-2:2018	measurement type	I 2022		To Program
62	IS 8254 (Part 1):	Valve, Non-Rebreathing - Part I :  Ruben's Pattern	January, 2023	-	Indigenous
		Ruben's Pattern			
63	Reviewed In: 2023	Value Non ushmoothing Dont H.	January 2022		Indiannas
63	IS 8254 (Part 2) : 1976	Value, Non-rebreathing - Part II : Ambu-hesse's Pattern	January, 2023	-	Indigenous
		Amou-nesse's Pattern			
64	Reviewed In: 2023 IS 8312: 1977	Espans Introducina Endatuschael	January 2010	1	Indianana
04	Reviewed In : 2019	Forceps, Introducing, Endotracheal	January, 2019	1	Indigenous
65	IS 8432 : 1977	Tube, Magill's Pattern Specification for tubes,	April, 2019	1	Indigenous
03		tracheostomy (Rubber Or Plastics)	Aprii, 2019	1	indigenous
66	IS/ISO 9170-2 :	Terminal units for medical gas	March, 2022		Identical under single
00	2008	pipeline systems: Part 2 terminal	iviaicii, 2022	1	numbering
		units for anaesthetic gas scavenging			numbering
	:2008	systems			
	Reviewed In: 2022	Systems			
	ISO 9170-2 :2008				
67	IS 9462 : 1980	Specification for humidifier,	January, 2023	_	Indigenous
"	Reviewed In : 2023	nebulizing, ventury type	January, 2023		margenous
	Reviewed III . 2023	neounzing, ventury type			1

# **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.	SI. No. Doc No. Title				
No Records Found					

		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	Anaesthetic and respiratory equipment Supralaryngeal airways and connectors First Revision			
	of: IS/ISO 11712:2009				

	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	Valve Non-Rebreathing Specification Part 1 Ruben s Pattern First Revision
	of: IS 8254:1976	
3	MHD 11 (18975) Revision	Specification for Valve Non-Rebreathing Part 2 Ambu-Hesses Pattern First Revision
	of: IS 8254:1976	
4	MHD 11 (19247) Revision	Drawover Portable Type Anaesthetic Apparatus - Specification Second Revision
	of: IS 7176:1985	
5	MHD 11 (22279) Revision	Medical Gas Pipeline Systems Part 1 Pipeline Systems for Compressed Medical Gases and
	of: IS/ISO 7396:2007	Vacuum First Revision
6	MHD 11 (22425)	Anaesthetic and Respiratory Equipment Tracheostomy Tubes and Connectors
7	MHD 11 (22610) Revision	Lung Ventilators Part 4 Particular Requirements for User Powered Resuscitators First Revision
	of: IS/ISO 10651:2002	
8	MHD 11 (22611) Revision	Anaesthetic and Respiratory Equipment-Tracheobronchial tubes First Revision
	of: IS/ISO 16628:2008	
9	MHD 11 (22613) Revision	Anaesthetic and Respiratory Equipment-Breathing Sets and Connectors
	of: IS/ISO 5367:2000	
10	MHD 11 (22615) Revision	Anaesthetic and Respiratory Equipment- Oropharyngeal Airways First Revision
	of: IS/ISO 5364:2008	
11	MHD 11 (22626)	Suction Catheters for Use in the Respiratory Tract
12	MHD 11 (24987) Revision	Anaesthetic and respiratory equipment Tracheal tubes and connectors First Revision
	of: IS/ISO 5361:1999	
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	ĺ
1	IS/ISO 10079-2 : 2014	Medical Suction Equipment Part 2 Manually Powered Suction Equipment First Revision	ı
	ISO 10079-2: 2014		ı
	Reviewed In: 2023 ISO		ı
	10079-2: 2014		ĺ
2	IS/ISO 10079-3 : 2014	Medical suction equipment Part 3 suction equipment powered from a vacuum or positive pressure	ı
	ISO 10079-3 : 2014	gas source First Revision	ĺ
	Reviewed In: 2023 ISO		ı
	10079-3 :2014		l

3	IS/ISO 10524-1 : 2006	Pressure Regulators For Use with Medical Gases Part 1 Pressure Regulators and Pressure
	ISO 10524-1:2006	Regulators with Flow-Metering Devices
	Reviewed In: 2023 ISO	
	10524-1:2006	
4	IS/ISO 10524-2 : 2005	Pressure Regulators for use with Medical Gases Part 2 Manifold and Line Pressure Regulators
	ISO10524-2:2005	
	Reviewed In:	
	2023 ISO10524-2:2005	
5	IS/ISO 10651-3:1997	Lung ventilators for medical use Part 3 particular requirements for emergency and transport
	ISO 10651-3 : 1997	ventilators
	Reviewed In: 2023 ISO	
	10651-3 : 1997	
6	IS/ISO 10651-6 : 2004	Lung ventilators for medical use - Particular requirements for basic safety and essential
	ISO 10651-6 : 2004	performance Part 6 home - Care ventilatory support devices
	Reviewed In: 2023 ISO	
	10651-6 : 2004	
7	IS 11363 : 1985	Tubes breathing for anaesthetic apparatus and ventilators
	ISO 5367	
	Reviewed In: 2011	
8	IS 11364 : 1994	Anaesthetic Reservoir Bags
	ISO 5362	
	Reviewed In: 2010	
9	IS 11807 : 1994	Oropharyngeal Airways
	ISO 5364	
	Reviewed In: 2010	
10	IS 11808 : 1986	Tracheal Tubes Connectors
	ISO 7228	
	Reviewed In: 2011	
11	IS 12504 (Part 1): 1988	Tracheal Tubes - Part 1 General Requirements
	ISO 5361-1	
10	Reviewed In : 2009	
12	IS 12504 (Part 2) : 1988 ISO 5361-2	Tracheal Tubes - Part 2 Oro-tracheal and Naso-tracheal Tubes of the Magill Type Plain and
	Reviewed In : 2010	Cuffed
13	IS 12504 (Part 4): 1988	Specification for Tracheal Tubes - Part 4 Cole Type
13	Reviewed In : 2004	Specification for Tractical Tubes - Latt 4 Cole Type
14	IS 12505 (Part 1): 1988	Tracheostomy Tubes Part 1 Connectors
14	ISO 5366-1	Tracheostony Tubes Fair F Connectors
	Reviewed In: 2010	
15	IS 12505 (Part 2) : 1988	Tracheostomy Tubes Part 2 Basic Requirements
15	ISO 5366-2	Tractic strong Ture 2 Busto recognitions
	Reviewed In: 2010	
16	IS 4113 (Part 1): 2003	Laryngoscopic fittings Part 1 conventional hook - On type handle - Blade fittings Second Revision
	ISO 7376 : Part 1	
	Reviewed In: 2023 ISO	
	7376 : Part 1	
17	IS 4113 (Part 2): 2003	Laryngoscopic fittings Part 2 miniature electric lamps - Screw threads and sockets for
	ISO 7376 : Part 2	conventional blades Second Revision
	Reviewed In: 2023 ISO	
	7376 : Part 2	
18	IS 4533 : 1995	Suction apparatus - Specification Second Revision
<u></u>	Reviewed In: 2021	
19	IS 5602 : 1970	Specification for Anaesthetic Breathing Bags
	Reviewed In: 2009	
20	IS 7409 (Part 1): 2003	Anaesthetic and Respiratory Equipment - Conical Connectors - Part 1 Cones and Sockets
	ISO 5356-1	
	Reviewed In: 2009	
21	IS 7409 (Part 2): 1994	Anaesthetic and respiratory equipment - Conical connectors Part 2 screw - Threaded weight -
	ISO 5356-2	Bearing connectors Second Revision
I	150 3330-2	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	Pressure regulators for use with medical gases- Part 3 Pressure regulators integrated with cylinder
	ISO 10524-2:2019	valves VIPRs First Revision
	ISO 26262-2:2018	
2	IS/ISO 10524-4 : 2008	Pressure regulators for use with medical gases Part 4 low - Pressure regulators
	ISO 10524 -4 :2008	
	Reviewed In: 2018 ISO	
	10524 -4 :2008	
3	IS/ISO 10651-4 : 2002	Lung ventilators for medical use - Particular requirements for basic safety and essential
	ISO 10651-4 : 2002	performance Part 4 particular requirements for operator - Powered resuscitators
	Reviewed In: 2023 ISO	
	10651-4 : 2002	
4	IS/ISO 10651-5 : 2006	Lung ventilators for medical use - Particular requirements for basic safety and essential
	ISO 10651-5 : 2006	performance Part 5 gas - Powered emergency resuscitators
	Reviewed In: 2023 ISO	
	10651-5 : 2006	
5	IS/ISO 11197 : 2019	Medical Supply Units First Revision
	ISO 11197:2019	
	ISO 16304:2018	
6	IS 11378 : 2002	Anaesthetic machines for use with humans First Revision
	ISO 5358	
	Reviewed In: 2017 ISO	
	5358	
7	IS/ISO 11712 : 2009	Anaesthetic and respiratory equipment - Supralaryngeal airways and connectors
	ISO 11712 : 2009	
	Reviewed In: 2019 ISO	
	11712 : 2009	
8	IS 12417 : 1988	Specification for suction apparatus pedal operated
	Reviewed In: 2019	
9	IS 13450 (Part 2/Sec 12):	Medical Electrical Equipment Part 2 Particular requirements for basic safety and essential
	2023	performance Section 12 Critical care ventilators First Revision
	ISO 80601-2-12:2020	
10	IS 13450 (Part 2/Sec 13):	Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential
	2024	Performance Sec 13 Anaesthetic Workstation First Revision
11	IS 13450 (Part 2/Sec 70):	Medical electrical equipment Part 2 - Particular requirements for basic safety and essential
	2022	performance Section 70 Sleep apnoea breathing therapy equipment
	ISO 80601-2-70:2020	
	ISO 8000-62 : 2022	
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 071R 19601 : 2017  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	Anaesthetic and Respiratory Equipment - Nebulizing Systems and Components
	Reviewed In : 2021 ISO 27427:2013	
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	Specification for mouth props and airways London Hospital Pattern
"-	Reviewed In: 2023	Specification for mount proposition and mayor Zondon frospital 2 attention
33	IS 4113 : 2022	Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation
	ISO 7376:2020	
34	IS 4154 : 1967	Specification for endotracheal connections
2.5	Reviewed In: 2018	
35	IS/ISO 5356-1 : 2015	Anaesthetic and respiratory equipment - Conical connectors Part 1 cones and sockets First
	ISO 5356-1 : 2015 Reviewed In : 2022 ISO	Revision
	5356-1:2015	
36	IS/ISO 5356-2 : 2012	Anaesthetic and respiratory equipment - Conical connectors Part 2 screw - Threaded weight -
	Reviewed In : 2020 ISO	Bearing connectors
	5356-2:2015	8.1. 1111 1
37	IS/ISO 5361 : 1999	Anaesthetic and respiratory equipment - Tracheal tubes and connectors
	ISO 5361	
	Reviewed In: 2022 ISO	
	5361	
38	IS/ISO 5362 : 2006	Anaesthetic reservoir bags
	ISO 5362 : 2006	
	Reviewed In : 2022 ISO 5362 : 2006	
39	IS/ISO 5364 : 2008	Anaesthetic and respiratory equipment - Oropharyngeal airways
	ISO 5364:2008	Anacsanctic and respiratory equipment. Oropharyngear an ways
	Reviewed In : 2019 ISO	
	5364 : 2008	
40	IS/ISO 5366-1 : 2000	Anaesthetic and respiratory equipment - Tracheostomy tubes Part 1 tubes and connectors for use
	ISO 5366 Part 1 : 2000	in adults
	Reviewed In: 2023 ISO	
41	5366 Part 1 : 2000	
41	IS/ISO 5367 : 2000 ISO 5367: 2000	Breathing tubes intended for use with anaesthetic apparatus and ventilators
	Reviewed In : 2022 ISO	
	5367: 2000	
42	IS 5622 : 1970	Soda-Lime Canisters for Use with Gas Anaesthetic Apparatus Waters to-and-Fro
	Reviewed In: 2021	••
43	IS 5680 : 1969	Specification for rubber tubing for medical use
	Reviewed In: 2020	
44	IS 6190: 1971	Specification for anaesthetic face masks
15	Reviewed In: 2019	
45	IS 6194 : 1971 Reviewed In : 2021	Specification for intermittent positive pressure respirator bag type manually operated
46	IS 6207 : 1971	Specification for trolleys for oxygen cylinders
10	Reviewed In : 2023	opecarication for troneys for oxygen cylinders
47	IS 6581 : 1972	Specification for endotracheal tubes Rubber
	Reviewed In: 2018	·
48	IS 6807 : 1972	Reinforced Flexo-metallic Magill s Endotracheal Tube
	Reviewed In: 2018	
49	IS 7176 : 1985	Specification for anaesthetic apparatus drawover portable type First Revision
50	Reviewed In : 2021	Co. Marsh Danier - Date
50	IS 7625 : 1975 Reviewed In : 2023	Gag Mouth Doyen s Pattern
51	IS 7652 : 1988	Specification for sphygmomanometer aneroid type First Revision
	Reviewed In : 2021	opechication for springmomation ancroid type i list Revision
52	IS 7885 : 1985	Spray Macintosh s Pattern
	Reviewed In: 2023	• •
53	IS/IEC 80601-2-30): 2018	Medical electrical equipment Part 2 - 30 particular requirements for basic safety and essential
	IEC80601-2-30:2018	performance of automated non - Invasive sphygmomanometers
	IEC 80601-2-30:2018	

	1	
54	IS/ISO 81060-1 : 2007	Non - Invasive sphygmomanometers Part 1 requirements and test methods for non - Automated
	IEC81060_1:2007	measurement type
	Reviewed In:	
	2023 IEC81060_1 : 2007	
55	IS 8254 (Part 1): 1976	Valve Non-Rebreathing - Part I Ruben s Pattern
	Reviewed In: 2023	
56	IS 8254 (Part 2): 1976	Value Non-rebreathing - Part II Ambu-hesse s Pattern
	Reviewed In: 2023	
57	IS 8312 : 1977	Forceps Introducing Endotracheal Tube Magill s Pattern
	Reviewed In: 2019	
58	IS 8432 : 1977	Specification for tubes tracheostomy Rubber Or Plastics
	Reviewed In: 2019	
59	IS/ISO 9170-2 : 2008	Terminal units for medical gas pipeline systems Part 2 terminal units for anaesthetic gas
	ISO 9170 : Part 2 :2008	scavenging systems
	Reviewed In: 2022 ISO	
	9170-2 :2008	
60	IS 9462 : 1980	Specification for humidifier nebulizing ventury type
	Reviewed In: 2023	