

BUREAU OF INDIAN STANDARDS

Program of Work

MHD 12 : Hospital Equipment and Surgical Disposable Products

Scope: To formulate Indian Standards for: i) Hospital equipment used in OPD wards and operation theaters such as Sterilizers, Incubators, hospital furniture, and operation tables etc. ii) Surgical disposable products like Transfusion, infusion and injection equipment etc., and devices for administration of medical product and intravascular catheters

Liaison: **ISO TC-76 (P):** *Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use* **ISO TC-84 (P):** *Devices for administration of medicinal products and catheters* **ISO TC-198 (P):** *Sterilization of health care products* **IEC TC-PC 130 (P):** *Cold Storage Equipment for Medical Use*

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS 10258 (Part 1):2022 7886-1:2017 7886-1:2017	Sterile hypodermic syringes for single use Part 1: Syringes for manual use Third Revision		-	Identical under dual numbering
2	IS 10258 (Part 2):2024 ISO 7886-2:2020 ISO 7886-2:2020	Sterile hypodermic syringes for single use Part 2 Syringes for use with power-driven syringe pumps		-	Identical under dual numbering
3	IS 10258 (Part 3):2021 ISO 7886-3:2020 ISO 7886-3:2020	Sterile hypodermic syringes for single use Part 3 Auto-disabled syringes for fixed-dose immunization First Revision		-	Identical under dual numbering
4	IS 10258 (Part 4):2024 ISO 7886-4:2018 ISO 7886-4:2018	Sterile Hypodermic Syringes for Single Use Part 4 Syringes with Re-use Prevention Feature		-	Identical under dual numbering
5	IS/ISO 10555-3:2013 ISO 10555-3 : 2013 Reviewed In : 2025 ISO 10555-3 : 2013	Intravascular catheters - Sterile and single - Use catheters: Part 3 central venous catheters (First Revision)	August, 2025	-	Identical under single numbering
6	IS/ISO 10555-5:2013 Reviewed In : 2025 ISO 10555-5:2013	Intravascular catheters - Sterile and single - Use catheters: Part 5 over - Needle peripheral catheters (First Revision)	August, 2025	-	Identical under single numbering
7	IS 10654:2018 ISO 7864 : 2016 Reviewed In : 2025 ISO 7864 : 2016 Ster	Sterile hypodermic needles for single use - Requirements and test methods (Fourth Revision)	July, 2025	-	Identical under dual numbering
8	IS 11040 (Part 1):2015	Prefilled syringes Part 1 : Glass cylinders for dental local		-	Identical under single numbering

	ISO 11040-1 : 2015 ISO 11040-1 : 2015	anaesthetic cartridges			
9	IS/ISO 11040-2:2011 ISO 11040-2:2011 ISO 11040-2:2011	Prefilled syringes Part 2 Plunger stoppers for dental local anaesthetic cartridges		-	Identical under single numbering
10	IS/ISO 11040-3:2012 ISO 11040-3:2012 ISO 11040-3:2012	Prefilled syringes Part 3 Seals for dental local anaesthetic cartridges		-	Identical under single numbering
11	IS/ISO 11040-4:2015 ISO 11040-4 : 2015 Reviewed In : 2025 ISO 11040-4 : 2015	Prefilled syringes Part 4 Glass barrels for injectables and sterilized subassembled syringes ready for filling	August, 2025	1	Identical under single numbering
12	IS/ISO 11040-5:2012 ISO 11040-5:2012 ISO 11040-5:2012	Prefilled syringes Part 5 Plunger stoppers for injectables		-	Identical under single numbering
13	IS 11043:1984 Reviewed In : 2025	Specification for needle, epidural	March, 2025	-	Indigenous
14	IS/ISO 11135:2014 ISO 11135 : 2014 Reviewed In : 2025 ISO 11135 : 2014	Sterilization of health - Care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	August, 2025	1	Identical under single numbering
15	IS/ISO 11137-1:2006 ISO 11137-1 : 2006 Reviewed In : 2025 ISO 11137-1 : 2006	Sterilization of health care products - Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices	August, 2025	1	Identical under dual numbering
16	IS/ISO 11137-2:2013 ISO 11137-2 : 2013 Reviewed In : 2025 ISO 11137-2 : 2013	Sterilization of health care products - Radiation: Part 2 establishing the sterilization dose	August, 2025	1	Identical under dual numbering
17	IS/ISO 11137-3:2017 ISO 11137-3 : 2017 ISO 11137-3 : 2017	Sterilization of Health Care Products • Radiation Part 3 Guidance on Dosimetric Aspects of Development, Validation and Routine Control		-	Identical under single numbering
18	IS/ISO 11138-1:2017 ISO 11138-1 : 2017 Reviewed In : 2025 ISO 11138-1 : 2017	Sterilization of Health Care Products • Biological Indicators Part 1 General Requirements	August, 2025	-	Identical under single numbering
19	IS/ISO 11138-2:2017 ISO 11138-2 : 2017 Reviewed In : 2025 ISO 11138-2 : 2017	Sterilization of Health Care Products • Biological Indicators Part 2 Biological Indicators for Ethylene Oxide Sterilization Processes	August, 2025	-	Identical under single numbering
20	IS/ISO 11138-3:2017 ISO 11138-3 : 2017 Reviewed In : 2025 ISO 11138-3 : 2017	Sterilization of Healthcare Products • Biological Indicators Part 3 Biological Indicators for Moist Heat Sterilization Processes	August, 2025	-	Identical under single numbering
21	IS/ISO	Sterilization of Health Care	August, 2025	-	Identical under single

	11138-4:2017 ISO 11138-4 : 2017 Reviewed In : 2025 ISO 11138-4 : 2017	Products • Biological Indicators Part 4 Biological Indicators for Dry Heat Sterilization Processes			numbering
22	IS/ISO 11138-5:2017 ISO 11138-5 : 2017 ISO 11138-5 : 2017	Sterilization of Health Care Products • Biological Indicators Part 5 Biological Indicators for Low-Temperature Steam and Formaldehyde Sterilization Processes		-	Identical under single numbering
23	IS/ISO 11140-3:2007 ISO 11140-3 : 2007 Reviewed In : 2025 ISO 11140-3 : 2007	Sterilization of health care products - Chemical indicators: Part 3 class 2 indicator systems for use in the bowie and dick - Type steam penetration test	August, 2025	-	Identical under single numbering
24	IS/ISO 11140-4:2007 ISO 11140-4 : 2007 Reviewed In : 2025 ISO 11140-4 : 2007	Sterilization of health care products - Chemical indicators: Part 4 class 2 indicators as an alternative to the bowie and dick - Type test for detection of steam penetration	August, 2025	-	Identical under single numbering
25	IS/ISO 11140-5:2007 ISO 11140-5 : 2007 Reviewed In : 2025 ISO 11140-5 : 2007	Sterilization of health care products - Chemical indicators: Part 5 class 2 indicators for bowie and dick - Type air removal tests	August, 2025	-	Identical under single numbering
26	IS/ISO 1135-3:2016 ISO 1135-3:2016 ISO 1135-3:2016	Transfusion equipment for medical use Part 3 Blood-taking sets for single use		-	Identical under single numbering
27	IS/ISO 1135-4:2015 ISO 1135-4 : 2015 ISO 1135-4 : 2015 Tr	Transfusion Equipment for Medical Use Part 4 Transfusion Sets for Single use, Gravity Feed		-	Identical under single numbering
28	IS/ISO 11418-1:2016 ISO 11418-1 : 2016 ISO 11418-1 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 1 Drop-Dispensing Glass		-	Identical under single numbering
29	IS/ISO 11418-2:2016 ISO 11418-2 : 2016 ISO 11418-2 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 2 Screw-Neck Glass Bottles for Syrups		-	Identical under single numbering
30	IS/ISO 11418-3:2016 ISO 11418-3 : 2016 ISO 11418-3 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 3 Screw-Neck Glass Bottles (Veral) for Solid and Liquid Dosage Forms		-	Identical under single numbering
31	IS/ISO 11418-5:2015 ISO 11418-5 : 2015 ISO 11418-5 : 2015	Containers and Accessories for Pharmaceutical Preparations Part 5 Dropper Assemblies		-	Identical under single numbering
32	IS/ISO 11418-7:2016 ISO 11418-7 : 2016 ISO 11418-7 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 7 Screw-Neck Vials Made of Glass Tubing for Liquid Dosage Forms		-	Identical under single numbering
33	IS/ISO 11607:2019 ISO 11607-1:2019 ISO 11607-1 : 2006	Packaging for terminally sterilized medical devices • Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision		1	Identical under single numbering

34	IS/ISO 11607:2019 ISO 11607-2:2019 Reviewed In : 2025 ISO 11607-2:2019	Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)	August, 2025	-	Identical under single numbering
35	IS/ISO 11737-1:2018 ISO 11737-1:2018 ISO 11737-1:2018	Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products		1	Identical under single numbering
36	IS/ISO 11737-2:2019 ISO 11737-2:2019 ISO 11737-2:2019	Sterilization of health care products Microbiological methods Part 2 Tests of sterility performed in the definition validation and maintenance of a sterilization process		-	Identical under single numbering
37	IS 12173:1987 Reviewed In : 2025	Specification for cervical halter	January, 2025	-	Indigenous
38	IS 12227:2020 ISO 8537 : 2016 Reviewed In : 2025 ISO 8537 : 2016 Ster	Sterile Single-Use Syringes, With or Without Needle, for Insulin (Second Revision)	January, 2025	-	Identical under dual numbering
39	IS 12430:1987 Reviewed In : 2025	Safety code for installation, servicing maintenanceand of sterilizers	January, 2025	-	Indigenous
40	IS/ISO 13408-1:2008 ISO 13408-1:2008 ISO 13408-1:2008	Aseptic processing of health care products Part 1 General requirements		-	Identical under single numbering
41	IS/ISO 13408-2:2018 ISO 13408-2:2018 Reviewed In : 2025 ISO 13408-2:2018	Aseptic processing of health care products Part 2 Sterilizing filtration	August, 2025	-	Identical under single numbering
42	IS 13422:2024 ISO 10282:2023 ISO 10282:2023	Single-use Sterile Rubber Surgical Gloves $\ddot{\iota}_{\mathfrak{c}}^{1/2}$ Specification (First Revision)		-	Identical under dual numbering
43	IS/ISO 13926-1:2018 ISO 13926-1:2018 ISO 13926-1:2018	Pen systems Part 1 Glass cylinders for pen-injectors for medical use		-	Identical under single numbering
44	IS/ISO 13926-2:2017 ISO 13926-2:2017 ISO 13926-2:2017	Pen systems Part 2 Plunger stoppers for pen-injectors for medical use		-	Identical under single numbering
45	IS B14316:1995 Reviewed In : 2025	Swabs, Small, in Bag of 50 (Bilingual)	July, 2025	-	
46	IS/ISO 14937:2009 ISO 14937:2009 Reviewed In : 2025 ISO 14937:2009	Sterilization of health care products General requirements for characterization of a sterilizing agent and the development validation and routine control of a sterilization process for medical devices	August, 2025	-	Identical under single numbering
47	IS 15113:2002 Reviewed In : 2025	Clinical electrical thermometers with maximum device - Specification	July, 2025	1	Indigenous
48	IS 15354 (Part 1):2023	Single-use medical examination gloves Part 1 Specification for		-	Identical under dual numbering

	ISO 11193-1:2020 ISO 11193-1:2020	gloves made from rubber latex or rubber solution Second Revision			
49	IS/ISO 15378:2017 IS/ISO 15378 : 2017 ISO 15378 : 2017	Primary Packaging Materials for Medicinal Products â€“ Particular Requirements for the Application of ISO 9001 : 2015, with Reference to Good Manufacturing Practice (GMP)		-	Identical under single numbering
50	IS 15537:2021 ISO 9187-1:2018 ISO 9187-1:2018	Injection equipment for medical use Part 1 Ampoules for injectables First Revision		-	Identical under dual numbering
51	IS 15537 (Part 2):2023 ISO 9187-2:2010 ISO 9187-2:2010	Injection equipment for medical use Part 2: One-point-cut OPC ampoules		-	Identical under dual numbering
52	IS/ISO 15883-1:2006 ISO 15883-1 : 2006 Reviewed In : 2025 ISO 15883-1 : 2006	Washer - Disinfectors: Part 1 general requirements, terms and definitions and tests	August, 2025	-	Identical under dual numbering
53	IS/ISO 15883-2:2006 ISO 15883-2 : 2006 Reviewed In : 2025 ISO 15883-2 : 2006	Washer - Disinfectors: Part 2 requirements and tests for washer - Disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc	August, 2025	-	Identical under single numbering
54	IS/ISO 15883-3:2006 ISO 15883-3 : 2006 Reviewed In : 2025 ISO 15883-3 : 2006	Washer - Disinfectors: Part 3 requirements and tests for washer - Disinfectors employing thermal disinfection for human waste containers	August, 2025	-	Identical under dual numbering
55	IS/ISO 15883-6:2011 ISO 15883-6 : 2011 ISO 15883-6 : 2011	Washer-disinfectors â€“ Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment		-	Identical under dual numbering
56	IS 16004:2024 ISO 6009:2016 ISO 6009:2016	Hypodermic Needles for Single Use $\frac{1}{2}$ Colour Coding for Identification (First Revision)		-	Identical under dual numbering
57	IS 16097:2013 Reviewed In : 2025	Sterile single use scalp vein (Winged Needle) infusion set	January, 2025	-	Indigenous
58	IS 17547:2021	Specification for Vaccine Freezer or Combined Vaccine Freezer and Water-Pack Freezer: Compression Cycle, General Requirements and Testing Methods		-	Indigenous
59	IS 17588:2021 0	Specification for Cold Box — General requirements and Test methods		-	Modified/Technically Equivalent
60	IS 17589:2021	Specification for Water Packs for use as ice-packs, cool-packs and warm-packs, Requirements and Test methods		-	Indigenous
61	IS 17964 (Part 7):2025 ISO 80369-7:2021 ISO 80369-7:2021	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic		-	Identical under dual numbering

		Applications			
62	IS 18240 (Part 89):2023 ISO 11139:2018 ISO 11139:2018	Sterilization of health care products Vocabulary of terms used in sterilization and related equipment and process standards		-	Identical under dual numbering
63	IS 18243:2023 ISO/TS 19930:2017 ISO/TS 19930:2017	Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10 ⁶		-	Identical under dual numbering
64	IS 18244:2023 ISO 21387:2020 ISO 21387:2020	Sterilization of medical devices Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release		-	Identical under dual numbering
65	IS 18245:2023 ISO/TS 16775:2021 ISO/TS 16775:2021	Packaging for terminally sterilized medical devices Guidance on the application of ISO 11607-1 and ISO 11607-2		-	Identical under dual numbering
66	IS 18287:2023 ISO/TS 22421 ISO/TS 22421	Sterilization of health care products Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities		-	Identical under dual numbering
67	IS 18288:2023 ISO 20696:2018 ISO 20696:2018	Sterile urethral catheters for single use		-	Identical under dual numbering
68	IS 18292 (Part 1):2024 ISO 10555-1:2023 ISO 10555-1:2023	Intravascular Catheters 1/2 Sterile and Single-Use Catheters Part 1 General Requirements		-	Identical under dual numbering
69	IS 18292 (Part 4):2024 ISO 10555-4:2023 ISO 10555-4:2023	Intravascular Catheters 1/2 Sterile and Single-Use Catheters Part 4 Balloon Dilatation Catheters (First Revision)		-	Identical under dual numbering
70	IS 18292 (Part 6):2023 ISO 10555-6:2015 ISO 10555-6:2015	Intravascular catheters Sterile and single-use catheters Part 6: Subcutaneous implanted ports		-	Identical under dual numbering
71	IS 18292 (Part 7):2024 ISO 10555-7:2023 ISO 10555-7:2023	Intravascular Catheters 1/2 Sterile and Single-Use Catheters Part 7 Peripherally Inserted Central Catheters		-	Identical under dual numbering
72	IS 18293 (Part 3):2023 ISO 13926-3:2019 ISO 13926-3:2019	Pen systems Part 3 Seals for pen-injectors for medical use		-	Identical under dual numbering
73	IS 18294 (Part 4):2023 ISO/TS11137-4:2020 ISO/TS11137-4:2020	Sterilization of health care products Radiation Part 4: Guidance on process control		-	Identical under dual numbering
74	IS 18319:2024 ISO 17665 : 2024	Sterilization of Health Care Products - Moist Heat -		-	Identical under dual numbering

	ISO 17665:2024	Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices (First Revision)			
75	IS 18344 (Part 4):2023 ISO 15883-4:2018 ISO 15883-4:2018	Washer-disinfectors Part 4 Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes		-	Identical under single numbering
76	IS 18446 (Part 6):2024 ISO 11140-6:2022 ISO 11140-6:2022	Sterilization of Health Care Products \ddagger Chemical Indicators Part 6 Type 2 Indicators and Process Challenge Devices for Use in Performance Testing of Small Steam Sterilizers		-	Identical under dual numbering
77	IS 18451:2023 ISO 20697:2018 ISO 20697:2018	Sterile drainage catheters and accessory devices for single use		-	Identical under dual numbering
78	IS 18446 (Part 1):2023 ISO 11140-1:2014 ISO 11140-1:2014	Sterilization of health care products Chemical indicators Part 1: General requirements		-	Identical under dual numbering
79	IS 18468 (Part 5):2024 ISO 15883-5:2021 ISO 15883-5:2021	Washer-disinfectors Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy		-	Identical under dual numbering
80	IS 18469 (Part 7):2023 ISO 11138-7:2019 ISO 11138-7:2019	Sterilization of health care products Biological indicators Part 7: Guidance for the selection use and interpretation of results		-	Identical under dual numbering
81	IS 18469 (Part 8):2023 ISO 11138-8:2021 ISO 11138-8:2021	Sterilization of health care products Biological indicators Part 8: Method for validation of a reduced incubation time for a biological indicator		-	Identical under dual numbering
82	IS 18474 (Part 5):2024 ISO 1135-5:2015 ISO 1135-5:2015	Transfusion equipment for medical use Part 5 Transfusion sets for single use with pressure infusion apparatus		-	Identical under dual numbering
83	IS 18478:2024 ISO 20698:2018 ISO 20698:2018	Catheter systems for neuraxial application Sterile and single-use catheters and accessories		-	Identical under dual numbering
84	IS 18529:2024 ISO 11070:2014 ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewire		-	Identical under dual numbering
85	IS 18618:2024 ISO/TS 5111:2022 ISO/TS 5111:2022	Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products		-	Identical under dual numbering
86	IS 18723:2024 ISO 6717:2021 ISO 6717:2021	In vitro diagnostic medical devices \ddagger Single-use containers for the collection of specimens from humans other than blood		-	Identical under dual numbering
87	IS 18730:2024 ISO 14160:2020 ISO 14160:2020	Sterilization of health care products \ddagger Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives \ddagger		-	Identical under dual numbering

		Requirements for characterization, development, validation and routine control of a sterilization process for medical devices			
88	IS 18735:2024 ISO 15747:2018 ISO 15747:2018	Plastic Containers for Intravenous Injections		-	Identical under dual numbering
89	IS 18735 (Part 1):2023	Medical Suction Equipment Part 1 Electrically Powered Suction Equipment		-	
90	IS 18742 (Part 1):2024 ISO 17664-1:2021 ISO 17664-1:2021	Processing of health care products <i>↳</i> Information to be provided by the medical device manufacturer for the processing of medical devices Part 1 Critical and semi-critical medical devices		-	Identical under dual numbering
91	IS 18742 (Part 2):2024 ISO 17664-2:2021 ISO 17664-2:2021	Processing of health care products <i>↳</i> Information to be provided by the medical device manufacturer for the processing of medical devices Part 2 Non-critical medical devices		-	Identical under dual numbering
92	IS 18744:2024 ISO 20069:2019 ISO 20069:2019	Guidance for assessment and evaluation of changes to drug delivery systems		-	Identical under dual numbering
93	IS 18855:2024 ISO/TS 23128:2019 ISO/TS 23128:2019	Medical Devices <i>↳</i> Transfusion Set and Blood Bag Compatibility Test Method		-	Identical under dual numbering
94	IS 18863 (Part 3):2024 ISO 11737-3:2023 ISO 11737-3:2023	Sterilization of Health Care Products <i>↳</i> Microbiological Methods Part 3 Bacterial Endotoxin Testing		-	Identical under dual numbering
95	IS 18866:2024 ISO 9626:2016 ISO 9626:2016	Stainless Steel Needle Tubing for the Manufacture of Medical Devices <i>↳</i> Requirements and Test Methods		-	Identical under dual numbering
96	IS 18871:2024 ISO 28620:2020 ISO 28620:2020	Medical Devices <i>↳</i> Non-Electrically Driven Portable Infusion Devices		-	Identical under dual numbering
97	IS 18872:2024 ISO 21881:2019 ISO 21881:2019	Sterile Packaged Ready for Filling Glass Cartridges		-	Identical under dual numbering
98	IS 18879 (Part 2):2024 ISO 8536-2:2023 ISO 8536-2:2023	Infusion Equipment for Medical Use Part 2 Closures for Infusion Bottles		-	Identical under dual numbering
99	IS 18879 (Part 3):2024 ISO 8536-3:2009+Amd1:2022 ISO 8536-3:2009+Amd1:2022	Infusion Equipment for Medical Use Part 3 Aluminium Caps for Infusion Bottles		-	Identical under dual numbering
100	IS 18879 (Part 5):2024 ISO 8536-5:2004 ISO 8536-5:2004	Infusion Equipment for Medical Use Part 5 Burette Infusion Sets for Single Use, Gravity Feed		-	Identical under dual numbering
101	IS 18879 (Part 6):2024	Infusion Equipment for Medical Use Part 6 Freeze Drying Closures		-	Identical under dual numbering

	ISO 8536-6:2016 ISO 8536-6:2016	for Infusion Bottles			
102	IS 18879 (Part 7):2024 ISO 8536-7:2009 ISO 8536-7:2009	Infusion Equipment for Medical Use Part 7 Caps Made of Aluminium-Plastics Combinations for Infusion Bottles		-	Identical under dual numbering
103	IS 18879 (Part 8):2024 ISO 8536-8:2015 ISO 8536-8:2015	Infusion equipment for medical use Part 8 Infusion sets for single use with pressure infusion apparatus		-	Identical under dual numbering
104	IS 18879 (Part 9):2024 ISO 8536-9:2015 ISO 8536-9:2015	Infusion Equipment for Medical Use Part 9 Fluid Lines for Single Use with Pressure Infusion Equipment		-	Identical under dual numbering
105	IS 18879 (Part 10):2024 ISO 8536-10:2015 ISO 8536-10:2015	Infusion Equipment for Medical Use Part 10 Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment		-	Identical under dual numbering
106	IS 18879 (Part 11):2024 ISO 8536-11:2015 ISO 8536-11:2015	Infusion Equipment for Medical Use Part 11 Infusion Filters for Single Use with Pressure Infusion Equipment		-	Identical under dual numbering
107	IS 18879 (Part 12):2024 ISO 8536-12:2021 ISO 8536-12:2021	Infusion Equipment for Medical Use Part 12 Check Valves for Single Use		-	Identical under dual numbering
108	IS 18879 (Part 13):2024 ISO 8536-13:2016 ISO 8536-13:2016	Infusion Equipment for Medical Use Part 13 Graduated Flow Regulators for Single Use with Fluid Contact		-	Identical under dual numbering
109	IS 18879 (Part 14):2024 ISO 8536-14:2016 ISO 8536-14:2016	Infusion Equipment for Medical Use Part 14 Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact		-	Identical under dual numbering
110	IS 18879 (Part 15):2024 ISO 8536-15:2022+ Amd1:2023 ISO 8536-15:2022+ Amd1:2023	Infusion Equipment for Medical Use Part 15 Light-Protective Infusion Sets for Single Use		-	Identical under dual numbering
111	IS 18880:2024 ISO 13004:2022 ISO 13004:2022	Sterilization of Health Care Products $\geq \frac{1}{2}$ Radiation $\geq \frac{1}{2}$ Substantiation of Selected Sterilization Dose: Method VDmaxSD		-	Identical under dual numbering
112	IS 18881 (Part 1):2025 ISO 13408-1:2023 ISO 13408-1:2023	Aseptic Processing of Health Care Products Part 1 General Requirements		-	Identical under dual numbering
113	IS 18881 (Part 3):2024 ISO 13408-3:2006 ISO 13408-3:2006	Aseptic Processing of Health Care Products Part 3 Lyophilization		-	Identical under dual numbering
114	IS 18881 (Part 4):2024 ISO 13408-4:2005 ISO 13408-4:2005	Aseptic Processing of Health Care Products Part 4 Clean-in-Place Technologies		-	Identical under dual numbering
115	IS 18881 (Part	Aseptic Processing of Health Care		-	Identical under dual

	5):2024 ISO 13408-5:2006 ISO 13408-5:2006	Products Part 5 Sterilization in Place			numbering
116	IS 18881 (Part 6):2024 ISO 13408-6:2021 ISO 13408-6:2021	Aseptic Processing of Health Care Products Part 6 Isolator Systems		-	Identical under dual numbering
117	IS 18881 (Part 7):2024 ISO 13408-7:2012 ISO 13408-7:2012	Aseptic Processing of Health Care Products Part 7 Alternative Processes for Medical Devices and Combination Products		-	Identical under dual numbering
118	IS 18980:2025	Blood Donor Couch		-	Indigenous
119	IS 18981:2025	Dialysis Chair		-	Indigenous
120	IS 19099:2025	Vaccine Carriers $\ddot{\text{c}}$ General Requirements and Test Methods		-	Indigenous
121	IS 19106:2025	Refrigerator or Combined Refrigerator and Water-Pack Freezer Intermittent Mains Powered $\ddot{\text{c}}$ Compression Cycle $\ddot{\text{c}}$ General Requirements and Test Methods		-	Indigenous
122	IS 19282 (Part 1):2025 ISO 11608-1:2022 ISO 11608-1:2022	Needle-Based Injection Systems for Medical Use $\ddot{\text{c}}$ Requirements and Test Methods Part 1 Needle-Based Injection Systems		-	Identical under dual numbering
123	IS 19282 (Part 2):2025 ISO 11608-2:2022 ISO 11608-2:2022	Needle-Based Injection Systems for Medical Use $\ddot{\text{c}}$ Requirements and Test Methods Part 2 Double-Ended Pen Needles		-	Identical under dual numbering
124	IS 19329 (Part 4):2025 ISO 11040-4:2024 ISO 11040-4:2024	Prefilled Syringes Part 4 Glass Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filling		-	Identical under dual numbering
125	IS 1984 (Part 1):2023 ISO 8362-1:2018 ISO 8362-1:2018	Injection containers and accessories Part 1 Injection vials made of glass tubing (First Revision)		-	Identical under dual numbering
126	IS 1984 (Part 2):2023 ISO 8362-4:2011 ISO 8362-4:2011	Injection containers and accessories Part 2 Injection vials made of moulded glass Third Revision		-	Identical under dual numbering
127	IS 1984 (Part 3):2023 ISO 8362-3:2001 ISO 8362-3:2001	Injection containers and accessories Part 3: Aluminum caps for injection vials		-	Identical under dual numbering
128	IS 17901:2025 ISO 8362-2:2024 ISO 8362-2:2024	Injection Containers and Accessories Part 4 Closures for Injection Vials (First Revision)		-	Identical under dual numbering
129	IS 1984 (Part 5):2024 ISO 8362-5:2016 ISO 8362-5:2016	Injection Containers and Accessories Part 5 Freeze Drying Closures for Injection Vials		-	Identical under dual numbering
130	IS 1984 (Part 6):2024 ISO 8362-6:2010 ISO 8362-6:2010	Injection Containers and Accessories Part 6 Caps Made of Aluminium-Plastics Combinations for Injection Vials		-	Identical under dual numbering
131	IS 3118:1978	Specification for electric	December, 2021	-	Indigenous

	Reviewed In : 2021	bacteriological incubators (First Revision)			
132	IS 3119:1978 Reviewed In : 2021	Specification for hot air sterilizers (First Revision)	December, 2021	-	Indigenous
133	IS/ISO 3826-1:2019 ISO 3826-1:2019 ISO 3826-1 : 2013	Plastics collapsible containers for human blood and blood components Part 1 Conventional containers First Revision		1	Identical under single numbering
134	IS/ISO 3826-2:2008 Reviewed In : 2025 ISO 3826-2 : 2008	Plastics collapsible containers for human blood and blood components: Part 2 graphical symbols for use on labels and instruction leaflets	August, 2025	-	Identical under single numbering
135	IS/ISO 3826-3:2006 ISO 3826-3 : 2008 Reviewed In : 2025 ISO 3826-3:2006	Plastics collapsible containers for human blood and blood components: Part 3 blood bag systems with integrated features	August, 2025	-	Identical under single numbering
136	IS/ISO 3826-4:2015 ISO 3826-4 : 2015 Reviewed In : 2025 ISO 3826-4 : 2015	Plastics Collapsible Containers for Human Blood and Blood Components Part 4 Aphaeresis Blood Bag Systems with Integrated Features	August, 2025	-	Identical under single numbering
137	IS 3829 (Part 1):1999 Reviewed In : 2025	Specification for steam sterilizers: Part 1 horizontal cylindrical and horizontal rectangular steam sterilizers, pressure type (For Hospital And Pharmaceutical Use) (Second Revision)	January, 2025	-	Indigenous
138	IS 3829 (Part 2):1978 Reviewed In : 2021	Specification for steam sterilizers: Part 2 horizontal cylindrical high speed steam sterilizers, pressure type (First Revision)	December, 2021	4	Indigenous
139	IS 3829 (Part 3):1985 Reviewed In : 2021	Specification for steam sterilizers: Part 3 pressure sterilizers, vertical cylindrical type	December, 2021	2	Indigenous
140	IS 3830:1979 Reviewed In : 2021	Specification for water stills for pyrogen - Free distilled water (Second Revision)	December, 2021	3	Indigenous
141	IS 3831:1979 Reviewed In : 2021	Specification for sterilizer, shallow (Dressing Drum)	December, 2021	4	Indigenous
142	IS 3992:1982 Reviewed In : 2021	Specification for trays, kidney (First Revision)	February, 2021	1	Indigenous
143	IS 3993:1993 Reviewed In : 2025	Trays, instruments - Specification (Second Revision)	January, 2025	-	Indigenous
144	IS 4033:1968 Reviewed In : 2021	General requirements for hospital furniture	December, 2021	1	Indigenous
145	IS 4035:1967 Reviewed In : 2021	Specification for trolleys, stretcher	December, 2021	1	Indigenous
146	IS 4036:1967 Reviewed In : 2021	Specification for trolleys, patient	December, 2021	-	Indigenous
147	IS 4037:1967 Reviewed In : 2021	Specification for stretchers and stretcher carriers	December, 2021	1	Indigenous
148	IS 4266:1967 Reviewed In : 2021	Specification for lockers, bedside for hospital use	December, 2021	3	Indigenous
149	IS 4267:1967 Reviewed In : 2021	Specification for stands, wash hand basin	December, 2021	-	Indigenous
150	IS 4445:2025	Filter and Filter Chamber for Blood Transfusion - Specification (First Revision)		-	Indigenous

151	IS 4455:1967 <i>Reviewed In : 2021</i>	Specification for trolleys, soiled linen	December, 2021	-	Indigenous
152	IS 4458:1967 <i>Reviewed In : 2021</i>	Specification for screens, bedside	December, 2021	-	Indigenous
153	IS 4494:1968 <i>Reviewed In : 2021</i>	Specification for tables, overbed	December, 2021	1	Indigenous
154	IS 4769:1968 <i>Reviewed In : 2021</i>	Specification for trolley, dressing	December, 2021	2	Indigenous
155	IS 4787:1968 <i>Reviewed In : 2021</i>	Specification for table, examination	December, 2021	1	Indigenous
156	IS 5022:1989 <i>Reviewed In : 2025</i>	Sterilizer, instruments, table model (Third Revision)	January, 2025	2	Indigenous
157	IS 5035:1969 <i>Reviewed In : 2021</i>	Specification for sterilizers, bowl and utensil (Pedal Type)	December, 2021	-	Indigenous
158	IS 5291:1969 <i>Reviewed In : 2021</i>	Specification for tables, operation, hydraulic, major	December, 2021	2	Indigenous
159	IS 5631:1970 <i>Reviewed In : 2021</i>	Specification for trolley, instrument, plain and curved	December, 2021	1	Indigenous
160	IS 5880:1970 <i>Reviewed In : 2021</i>	Specification for stand, saline - Cum - Irrigator	December, 2021	-	Indigenous
161	IS 6083:1971 <i>Reviewed In : 2021</i>	Specification for table, obstetric, labour	December, 2021	1	Indigenous
162	IS 6106:1971 <i>Reviewed In : 2021</i>	Specification for tables, operation, hydraulic, minor	December, 2021	3	Indigenous
163	IS 6328:1971 <i>Reviewed In : 2021</i>	Specification for table, operation, general purposes (Non - Hydraulic)	December, 2021	-	Indigenous
164	IS 6593:1972 <i>Reviewed In : 2021</i>	Specification for electric serological water - Baths	December, 2021	3	Indigenous
165	IS 6904:1973 <i>Reviewed In : 2021</i>	Specification for receptacle, waste	December, 2021	-	Indigenous
166	IS 6905:1973 <i>Reviewed In : 2021</i>	Instruments Table, Mayo's Type	December, 2021	1	Indigenous
167	IS 7083:1973 <i>Reviewed In : 2021</i>	Specification for trolley, medicine	December, 2021	2	Indigenous
168	IS 7091:1973 <i>Reviewed In : 2021</i>	Specification for lifter, bed, adjustable	December, 2021	-	Indigenous
169	IS 7099:1973 <i>Reviewed In : 2021</i>	Specification for trolley, dressing drum	December, 2021	-	Indigenous
170	IS 7350:1974 <i>Reviewed In : 2025</i>	Specification for needles, spinal	January, 2025	1	Indigenous
171	IS 7378:1974 <i>Reviewed In : 2021</i>	Bed, Fowler's, Hospital	December, 2021	2	Indigenous
172	IS 7387:1974 <i>Reviewed In : 2025</i>	Needle, Biopsy, Liver, Silverman's Pattern	January, 2025	-	Indigenous
173	IS 7596:1974 <i>Reviewed In : 2021</i>	Table, Operation, Orthopaedic, Albee's Type	December, 2021	-	Indigenous
174	IS/ISO 80369-7:2016 ISO 80369-7 : 2016 <i>ISO 80369-7</i>	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications		-	Identical under single numbering
175	IS 8078:1976 <i>Reviewed In : 2021</i>	Specification for table, operation, paediatric	December, 2021	-	Indigenous
176	IS 8079:1976 <i>Reviewed In : 2021</i>	Specification for table, operation, urological	December, 2021	-	Indigenous
177	IS 8462:1977 <i>Reviewed In : 2021</i>	Specification for sterilizer, portable, vertical, pressure type	December, 2021	3	Indigenous
178	IS B8462:1977 <i>Reviewed In : 2016</i>	Sterilizer, Portable, Vertical, Pressure Type (BI-LINGUAL)	December, 2016	3	Indigenous

179	IS/ISO 8536-1:2011 ISO 8536-1:2011 ISO 8536-1:2011	Infusion equipment for medical use Part 1 Infusion glass bottles		-	Identical under dual numbering
180	IS/ISO 8536-4:2019 ISO 8536-4:2019 ISO 8536-4:2019	Infusion equipment for medical use Part 4: Infusion sets for single use gravity feed		-	Identical under single numbering
181	IS 9132:1979 Reviewed In : 2021	Specification for table, operation, folding type	December, 2021	-	Indigenous
182	IS 9133:1979 Reviewed In : 2021	Specification for trolley for general medical store	December, 2021	-	Indigenous

Standards under Development

Projects Approved

SI. No.	Doc No.	Title
1	MHD 12 (28317)	Washer-Disinfectors Part 7 Requirements and Tests for Washer-Disinfectors Employing Chemical Disinfection for Non-Critical Thermolabile Medical Devices and Health Care equipment

Preliminary Draft Standards

SI. No.	Doc No.	Title
1	MHD 12 (26308)	Walk-in-Freezer General Requirements and Test Methods
2	MHD 12 (26309)	Vaccine Refrigerator or Combined Refrigerator and Water-Pack Freezer Powered by Solar Direct Drive System with No Battery General Requirements and Test Methods

Drafts Standards in WC Stage

SI. No.	Doc No.	Title
1	MHD 12 (27699)	Walk-in Cooler Specification Temperature Range of 2 C to 8 C
2	MHD 12 (28624) Amendment of: IS 5022:1989	Table Model Type Instrument Sterilizer - Specification Fourth Revision
3	MHD 12 (28625) Amendment of: IS 5035:1969	Pedal Type Bowl and Utensil Sterilizer - Specification First Revision
4	MHD 12 (28634) Amendment of: IS 7378:1974	Manual Fowler Beds Requirements and Dimensional Details First Revision
5	MHD 12 (28635)	Burn Sheet Specification

Draft Standards Completed WC Stage

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

Finalized Draft Indian Standard

SI. No.	Doc No.	Title
1	MHD 12 (28304)	Elastomeric Parts for Parenterals and for Devices for Pharmaceutical Use Part 2 Identification and Characterization
2	MHD 12 (28307)	Elastomeric Parts for Parenterals and for Devices for Pharmaceutical Use Part 5 Functional Requirements and Testing
3	MHD 12 (28309)	Prefilled Syringes Part 6 Plastic Barrels for Injectables and Sterilized Subassembled Syringes Ready for Filling
4	MHD 12 (28310)	Prefilled Syringes Part 7 Packaging Systems for Sterilized Subassembled Syringes Ready for Filling
		Prefilled Syringes Part 8 Requirements and Test Methods for Finished Prefilled Syringes

5	MHD 12 (28311)	
6	MHD 12 (28312)	Needle-Based Injection Systems for Medical Use Requirements and Test Methods Part 3 Containers and Integrated Fluid Paths
7	MHD 12 (28316)	Needle-Based Injection Systems for Medical Use Requirements and Test Methods Part 7 Accessibility for Persons with Visual Impairment
8	MHD 12 (28318)	Intravascular Catheters Sterile and Single-Use Catheters Part 8 Catheters for Extracorporeal Blood Treatment

Finalized Draft Indian Standards under Print

Sl. No.	Doc No.	Title
1	MHD 12 (28293)	Transfusion Equipment for Medical Use Part 4 Transfusion Sets for Single Use Gravity Feed
2	MHD 12 (28294) Amendment of: IS 18474:2024	Transfusion Equipment for Medical Use Part 5 Transfusion Sets for Single Use with Pressure Infusion Apparatus First Revision
3	MHD 12 (28295) Amendment of: IS 18879:2024	Infusion Equipment for Medical Use Part 6 Freeze Drying Closures for Infusion Bottles First Revision
4	MHD 12 (28296) Amendment of: IS 18879:2024	Infusion Equipment for Medical Use Part 13 Graduated Flow Regulators for Single Use with Fluid Contact First Revision
5	MHD 12 (28298)	Sterilization of Health Care Products Radiation Part 1 Requirements for the Development Validation and Routine Control of a Sterilization Process for Medical Devices
6	MHD 12 (28299)	Washer-Disinfectors Part 1 General Requirements Terms and Definitions and Tests
7	MHD 12 (28300)	Washer-Disinfectors Part 2 Requirements and Tests for Washer-Disinfectors Employing Thermal Disinfection for Critical and Semi-Critical Medical Devices
8	MHD 12 (28301)	Washer-Disinfectors Part 3 Requirements and Tests for Washer-Disinfectors Employing Thermal Disinfection for Human Waste Containers
9	MHD 12 (28302)	Injection Containers and Accessories Part 7 Injection Caps Made of Aluminium-Plastics Combinations Without Overlapping Plastics Part
10	MHD 12 (28303)	Elastomeric Parts for Parenterals and for Devices for Pharmaceutical Use Part 1 Extractables in Aqueous Autoclavates
11	MHD 12 (28305)	Elastomeric Parts for Parenterals and for Devices for Pharmaceutical Use Part 3 Determination of Released-Particle Count
12	MHD 12 (28306)	Elastomeric Parts for Parenterals and for Devices for Pharmaceutical Use Part 4 Biological Requirements and Test Methods
13	MHD 12 (28308)	Aluminium Caps and Aluminium Plastic Caps for Infusion Bottles and Injection Vials General Requirements and Test Methods
14	MHD 12 (28313)	Needle-Based Injection Systems for Medical Use Requirements and Test Methods Part 4 Needle-Based Injection Systems Containing Electronics
15	MHD 12 (28314)	Needle-Based Injection Systems for Medical Use Requirements and Test Methods Part 5 Automated Functions
16	MHD 12 (28315)	Needle-Based Injection Systems for Medical Use Requirements and Test Methods Part 6 On-body Delivery Systems
17	MHD 12 (28615) Amendment of: IS 11043:1984	Epidural Needle Specification First Revision
18	MHD 12 (28616) Amendment of: IS 3119:1978	Hot Air Sterilizers Specification Second Revision
19	MHD 12 (28618) Amendment of: IS 3829:1999	Steam Sterilizers Specification Part 1 Pressure Type Horizontal Cylindrical and Horizontal Rectangular Steam Sterilizers Third Revision
20	MHD 12 (28619) Amendment of: IS 3829:1978	Steam Sterilizers Specification Part 2 Pressure Type Horizontal Cylindrical High Speed Steam Sterilizers Second Revision
21	MHD 12 (28621) Amendment of: IS 3829:1985	Steam Sterilizers Specification Part 3 Vertical Cylindrical Pressure Sterilizers First Revision

22	MHD 12 (28622) Amendment of: IS 3831:1979	Shallow Sterilizer Dressing Drum Specification Third Revision
23	MHD 12 (28623) Amendment of: IS 3993:1993	Instrument Tray Specification Third Revision
24	MHD 12 (28626) Amendment of: IS 4035:1967	Stretcher Trolley - Specification First Revision
25	MHD 12 (28627) Amendment of: IS 4036:1967	Patient Trolley - Specification First Revision
26	MHD 12 (28628) Amendment of: IS 4037:1967	Stretchers and Stretcher Carriers - Specification First Revision
27	MHD 12 (28630) Amendment of: IS 4266:1967	Bedside Locker for Hospital Use - Specification First Revision
28	MHD 12 (28631) Amendment of: IS 4267:1967	Hand Wash Basin and Stand - Specification First Revision
29	MHD 12 (28632) Amendment of: IS 4458:1967	Bedside Screens - Specification First Revision
30	MHD 12 (28633) Amendment of: IS 7350:1974	Spinal Needle Specification First Revision
31	MHD 12 (28657)	Sterilization of health care products Low temperature vaporized hydrogen peroxide Requirements for the development validation and routine control of a sterilization process for medical devices
32	MHD 12 (33288)	Hospital Furniture - General Requirements First Revision

Total Published Standards:118 Total Standards Under development:48

Aspect Wise Report

Product : 137
 Code of Practices : 13
 Methods of Test : 6
 Terminology : 1
 Dimensions : 0
 System Standard : 0
 Safety Standard : 0
 Others : 10
 Service Specification : 0
 Process Specification : 12
 Unclassified : 2

Annexure-I :List of Indian Standards Withdrawn/Superseded

SI. No.	IS No. & Year	Title
1	IS 10150:1981 Reviewed In : 2021	Guide for sterilization of medical products
2	IS 10263:1982 Reviewed In : 2021	Specification for deep fat fryer single and double pan electrically operated for large catering establishments
3	IS 10264:1982 Reviewed In : 2021	Specification for trolley hot food for hospital and industrial canteen - Ns
4	IS/ISO 10555-1:2013 ISO 10555-1 : 2013 ISO 10555-1 : 2013	Intravascular catheters - Sterile and single - Use catheters Part 1 general requirements First Revision

5	IS/ISO 10555-2:1996 Reviewed In : 2014	Sterile single-use intravascular catheters-Part 2 Angiographic Catheters
6	IS/ISO 10555-4:2013 ISO 10555-4 : 2013 Reviewed In : 2025	Intravascular Catheters Sterile and Single-Use Catheters Part 4 Balloon Dilatation Catheters First Revision
7	IS 10603:1983 Reviewed In : 2021	Specification for abdominal belts
8	IS 10783:1983 Reviewed In : 2021	Specification for patient - Lifting devices mobile manually operated
9	IS 10985:1984 Reviewed In : 2017	Specification for needle acupuncture
10	IS 1108:1975 Reviewed In : 2017	Specification for pharmaceutical glass containers Second Revision
11	IS 11400:1985 Reviewed In : 2017	Specification for hypodermic syringes interchangeable type for general purposes
12	IS 12050:1986 Reviewed In : 2017	Specification for sterile hypodermic syringes with needle attached for single use
13	IS 12227:2002 ISO 8537 Reviewed In : 2012 Identical	Sterile Single-Use Syringes With or Without Needle for Insulin
14	IS 12655 (Part 4):2003 ISO 8536-4 Reviewed In : 2018 ISO 8536-4	Infusion equipment for medical use Part 4 infusion sets for single use gravity feed First Revision
15	IS 13115:1991 Reviewed In : 2021	Portable first - Aid kit for general use - Specification
16	IS B13115:1991 Reviewed In : 2016	Portable First Aid Kit for General Use Bi-lingual
17	IS/ISO 14161:2009 ISO 14161 : 2009 ISO 14161 : 2009	Sterilization of health care products - Biological indicators - Guidance for the selection use and interpretation of results
18	IS 14193:1994 Reviewed In : 2021	Ovulation thermometers - Specification
19	IS 15102:2002 ISO 3826 Reviewed In : 2017	Plastics Collapsible Containers for Human Blood and Blood Components
20	IS 15110:2002 Reviewed In : 2017	Veterinary thermometers mercury - In - Glass type - Specification
21	IS 15354:2003 ISO 11193 Reviewed In : 2014	Single-Use Rubber Examination Gloves
22	IS 15354 (Part 2):2018 ISO 11193-2 : 2006 ISO 11193-2 : 2006	Single - Use medical examination gloves Part 2 specification for gloves made from poly Vinyl Chloride First Revision
23	IS/ISO/TS 15883-5:2005 ISO/TS 15883-5 : 2000 ISO/ TS 11669	Washer-disinfectors Part 5 Test soils and methods for demonstrating cleaning efficacy
24	IS/ISO 17664:2017 ISO 17664:2017 ISO/IEC 23736-3: 2020	Processing of health care products Information to be provided by the medical device manufacturer for the processing of medical devices
25	IS 1984 (Part 1):2003 ISO 8362-1 Reviewed In : 2008	Injection Containers for Injectables and Accessories - Part 1 Injection Vials Made of Glass Tubing
26	IS 3120:1999 Reviewed In : 2019	Baby incubators - Specification Second Revision
27	IS 3234 (Part 1):1986 ISO 594-1 Reviewed In : 2017 ISO	Specification for conical fittings with a 6 Luer taper for syringes needles and other medical equipment Part 1 general requirements Second Revision

	594-1	
28	IS 3234 (Part 2):1995 ISO 594-2 Reviewed In : 2016 ISO 594-2	Conical fITtNgs with a 6 Luer taper for syringes needles and certain other medical equipment Part 2 lock fittings
29	IS 3235:1988 ISO 595-2 Reviewed In : 2021 ISO 595-2	General requirements for syringes for medical use Second Revision
30	IS 3236:1992 Reviewed In : 2018 ISO 595-1	Hypodermic syringes for general purposes - Specification Second Revision
31	IS 3237 (Part 1):1985 Reviewed In : 2017	Specification for special purpose syringes Part 1 insulin syringes Second Revision
32	IS 3237 (Part 2):1985 Reviewed In : 2017 ISO 594-2	Specification for special purpose syringes Part 2 tuberculin syringes Second Revision
33	IS 3237 (Part 3):1985 Reviewed In : 2017	Specification for special purpose syringes Part 3 bcg syringes Second Revision
34	IS 3237 (Part 4):1986 Reviewed In : 2017	Specification for special purpose syringes Part 4 vaccine syringe
35	IS 3237 (Part 5):1986 Reviewed In : 2017	Specification for special purpose syringes Part 5 post operation care syringe Second Revision
36	IS 3237 (Part 6):1986 Reviewed In : 2017	Specification for special purpose syringes Part 6 irrigation syringe
37	IS 3237 (Part 7):1986 Reviewed In : 2017	Specification for special purpose syringe Part 7 forced feeding syringe
38	IS 3237 (Part 8):1986 Reviewed In : 2017	Specification for special purpose syringes Part 8 angiography syringe
39	IS 3423:1973 Reviewed In : 2018	Specification for glass contafners for transfusion fluids First Revision
40	IS 3994:1993 Reviewed In : 2019	Bowls wash - Specification Second Revision
41	IS 3997:1982 Reviewed In : 2021	Specification for jars ointment First Revision
42	IS 3998:1982 Reviewed In : 2006	Cups Medicine
43	IS 4034:1979 Reviewed In : 2021	Specification for castors for hospital equipment First Revision
44	IS 4068:1967 Reviewed In : 2007	Specification for broken brick Burnt Clay coarse aggregate for use in lime concrete
45	IS 4148:1989 Reviewed In : 2021	Surgical rubber gloves - Specification First Revision
46	IS 4363:1980 Reviewed In : 2017	Specification for drip counter E M S pattern First Revision
47	IS 4510:1978	Redesignated as IS 3829 Part 2
48	IS 489 (Part 1):1973 Reviewed In : 2008	Glass Ampoules - Part I Ampoules for Liquid Injectables
49	IS 489 (Part 2):1973 Reviewed In : 2003	Glass Ampoules - Part II Ampoules for lyophilized injectable
50	IS 490:1967	Vaccine Phials
51	IS 5029:1979 Reviewed In : 2021	Specification for bedsteads hospital general purposes First Revision
52	IS 5156:1969	Calorimeter Cup Duboscq Type
53	IS 5335:1969	Tables bedsides

54	IS 5336:1969 Reviewed In : 2021	Specification for back rest
55	IS 5337:1969 Reviewed In : 2021	Specification for cot dropside baby hospital
56	IS 5630:1994 Reviewed In : 2019	Crib Cradles maternity - Specification First Revision
57	IS 5764:1994	Bowls Solution
58	IS 5782:1994	Bowls Sponge
59	IS 6208:1971 Reviewed In : 2017	Specification for spoons plastics measuring medicine
60	IS 6877:1977 Reviewed In : 2021 ISO 20795-1 : 2013	Specification for cabinet instruments First Revision
61	IS 7036:1982 Reviewed In : 2021	Specification for table postmortem First Revision
62	IS 7081:1973 Reviewed In : 2019	Specification for stool revolving for hospital use
63	IS 7171:1974 Reviewed In : 2017	Specification for drip counter with filter
64	IS 7455:1974 Reviewed In : 2021	Specification for sterilizer pressure hot and cold water
65	IS 7523:1974 Reviewed In : 2017	Specification for rubber catheter Urinary
66	IS/ISO 8362-1:2003 ISO8362-1:2003 Reviewed In : 2019 ISO8362-1:2003	Injection containers and accessories Part 1 injection vials made of glass tubing
67	IS 9395:1979 Reviewed In : 2016	Specification for bed intensive care
68	IS 9824 (Part 1):1996 ISO 1135-1 Reviewed In : 2018 ISO 1135-1	Transfusion equipment for medical use - Specification Part 1 glass transfusion bottles closures and caps First Revision
69	IS 9824 (Part 2):1995 ISO 1135-3 Reviewed In : 2016 ISO 1135-3	Transfusion equipment for medical use - Specification Part 2 blood - Taking set for single use First Revision
70	IS 9824 (Part 3):1996 ISO 1135-4 Reviewed In : 2018 ISO 1135-4	Transfusion equipment for medical use - Specification Part 3 transfusion set for single use First Revision

Annexure-II :List of Indian Product Standards

SI. No.	IS No. & Year	Title
1	IS 10258 (Part 1):2022 7886-1:2017 IEC 63203-201-3: 2021	Sterile hypodermic syringes for single use Part 1 Syringes for manual use Third Revision
2	IS 10258 (Part 2):2024 ISO 7886-2:2020	Sterile hypodermic syringes for single use Part 2 Syringes for use with power-driven syringe pumps
3	IS 10258 (Part 3):2021 ISO 7886-3:2020	Sterile hypodermic syringes for single use Part 3 Auto-disabled syringes for fixed-dose immunization First Revision
4	IS 10258 (Part 4):2024 ISO 7886-4:2018	Sterile Hypodermic Syringes for Single Use Part 4 Syringes with Re-use Prevention Feature

5	IS/ISO 10555-3:2013 ISO 10555-3 : 2013 Reviewed In : 2025 ISO 10555-3 : 2013	Intravascular catheters - Sterile and single - Use catheters Part 3 central venous catheters First Revision
6	IS/ISO 10555-5:2013 Reviewed In : 2025 ISO 10555-5:2013	Intravascular catheters - Sterile and single - Use catheters Part 5 over - Needle peripheral catheters First Revision
7	IS 10654:2018 ISO 7864 : 2016 Reviewed In : 2025 ISO 7864 : 2016 Ster	Sterile hypodermic needles for single use - Requirements and test methods Fourth Revision
8	IS 11040 (Part 1):2015 ISO 11040-1 : 2015	Prefilled syringes Part 1 Glass cylinders for dental local anaesthetic cartridges
9	IS/ISO 11040-2:2011 ISO 11040-2:2011 ISO 13579-1: 2013	Prefilled syringes Part 2 Plunger stoppers for dental local anaesthetic cartridges
10	IS/ISO 11040-3:2012 ISO 11040-3:2012 ISO 13579-2 : 2013	Prefilled syringes Part 3 Seals for dental local anaesthetic cartridges
11	IS/ISO 11040-4:2015 ISO 11040-4 : 2015 Reviewed In : 2025 ISO 18250-8:2018	Prefilled syringes Part 4 Glass barrels for injectables and sterilized subassembled syringes ready for filling
12	IS/ISO 11040-5:2012 ISO 11040-5:2012 ISO 1039:1995	Prefilled syringes Part 5 Plunger stoppers for injectables
13	IS 11043:1984 Reviewed In : 2025	Specification for needle epidural
14	IS/ISO 11138-1:2017 ISO 11138-1 : 2017 Reviewed In : 2025 ISO 11138-1 : 2017	Sterilization of Health Care Products Biological Indicators Part 1 General Requirements
15	IS/ISO 11138-2:2017 ISO 11138-2 : 2017 Reviewed In : 2025 ISO 11138-2 : 2017	Sterilization of Health Care Products Biological Indicators Part 2 Biological Indicators for Ethylene Oxide Sterilization Processes
16	IS/ISO 11138-3:2017 ISO 11138-3 : 2017 Reviewed In : 2025 ISO 11138-3 : 2017	Sterilization of Healthcare Products Biological Indicators Part 3 Biological Indicators for Moist Heat Sterilization Processes
17	IS/ISO 11138-4:2017 ISO 11138-4 : 2017 Reviewed In : 2025 ISO 11138-4 : 2017	Sterilization of Health Care Products Biological Indicators Part 4 Biological Indicators for Dry Heat Sterilization Processes
18	IS/ISO 11138-5:2017 ISO 11138-5 : 2017 ISO 11138-5 : 2017	Sterilization of Health Care Products Biological Indicators Part 5 Biological Indicators for Low-Temperature Steam and Formaldehyde Sterilization Processes
19	IS/ISO 1135-3:2016 ISO 1135-3:2016	Transfusion equipment for medical use Part 3 Blood-taking sets for single use
20	IS/ISO 1135-4:2015 ISO 1135-4 : 2015 ISO 1135-4 : 2015 Tr	Transfusion Equipment for Medical Use Part 4 Transfusion Sets for Single use Gravity Feed
21	IS/ISO 11418-1:2016 ISO 11418-1 : 2016 ISO 11418-1 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 1 Drop-Dispensing Glass
22	IS/ISO 11418-2:2016	Containers and Accessories for Pharmaceutical Preparations Part 2 Screw-Neck Glass Bottles for

	ISO 11418-2 : 2016 ISO 11418-2 : 2016	Syrups
23	IS/ISO 11418-3:2016 ISO 11418-3 : 2016 ISO 11418-3 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 3 Screw-Neck Glass Bottles Veral for Solid and Liquid Dosage Forms
24	IS/ISO 11418-5:2015 ISO 11418-5 : 2015 ISO 11418-5 : 2015	Containers and Accessories for Pharmaceutical Preparations Part 5 Dropper Assemblies
25	IS/ISO 11418-7:2016 ISO 11418-7 : 2016 ISO 11418-7 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 7 Screw-Neck Vials Made of Glass Tubing for Liquid Dosage Forms
26	IS 12173:1987 Reviewed In : 2025	Specification for cervical halter
27	IS 13422:2024 ISO 10282:2023	Single-use Sterile Rubber Surgical Gloves Specification First Revision
28	IS/ISO 13926-1:2018 ISO 13926-1:2018 22123 Part 1:2021	Pen systems Part 1 Glass cylinders for pen-injectors for medical use
29	IS/ISO 13926-2:2017 ISO 13926-2:2017 ISO 17179 : 2016	Pen systems Part 2 Plunger stoppers for pen-injectors for medical use
30	IS B14316:1995 Reviewed In : 2025	Swabs Small in Bag of 50 Bi-lingual
31	IS 15113:2002 Reviewed In : 2025	Clinical electrical thermometers with maximum device - Specification
32	IS 15354 (Part 1):2023 ISO 11193-1:2020	Single-use medical examination gloves Part 1 Specification for gloves made from rubber latex or rubber solution Second Revision
33	IS 15537:2021 ISO 9187-1:2018 ISO 48-4:2018	Injection equipment for medical use Part 1 Ampoules for injectables First Revision
34	IS 15537 (Part 2):2023 ISO 9187-2:2010	Injection equipment for medical use Part 2 One-point-cut OPC ampoules
35	IS/ISO 15883-1:2006 ISO 15883-1 : 2006 Reviewed In : 2025 ISO 15883-1 : 2006	Washer - Disinfectors Part 1 general requirements terms and definitions and tests
36	IS 16097:2013 Reviewed In : 2025	Sterile single use scalp vein Winged Needle infusion set
37	IS 17547:2021 ISO 3601-3:2005	Specification for Vaccine Freezer or Combined Vaccine Freezer and Water-Pack Freezer Compression Cycle General Requirements and Testing Methods
38	IS 17588:2021 ISO 3601-4:2008	Specification for Cold Box General requirements and Test methods
39	IS 17589:2021 ISO 16014-4 : 2019	Specification for Water Packs for use as ice-packs cool-packs and warm-packs Requirements and Test methods
40	IS 17964 (Part 7):2025 ISO 80369-7:2021	Small-Bore Connectors for Liquids and Gases in Healthcare Applications Part 7 Connectors for Intravascular or Hypodermic Applications
41	IS 18287:2023 ISO/TS 22421	Sterilization of health care products Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities
42	IS 18288:2023 ISO 20696:2018	Sterile urethral catheters for single use
43	IS 18292 (Part 1):2024 ISO 10555-1:2023	Intravascular Catheters Sterile and Single-Use Catheters Part 1 General Requirements

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45	IS 18292 (Part 6):2023 ISO 10555-6:2015	Intravascular catheters Sterile and single-use catheters Part 6 Subcutaneous implanted ports
46	IS 18292 (Part 7):2024 ISO 10555-7:2023	Intravascular Catheters Sterile and Single-Use Catheters Part 7 Peripherally Inserted Central Catheters
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49	IS 18451:2023 ISO 20697:2018	Sterile drainage catheters and accessory devices for single use
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51	IS 18474 (Part 5):2024 ISO 1135-5:2015	Transfusion equipment for medical use Part 5 Transfusion sets for single use with pressure infusion apparatus
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59	IS 18879 (Part 2):2024 ISO 8536-2:2023	Infusion Equipment for Medical Use Part 2 Closures for Infusion Bottles
60	IS 18879 (Part 3):2024 ISO 8536-3:2009+Amd1:2022	Infusion Equipment for Medical Use Part 3 Aluminium Caps for Infusion Bottles
61	IS 18879 (Part 5):2024 ISO 8536-5:2004	Infusion Equipment for Medical Use Part 5 Burette Infusion Sets for Single Use Gravity Feed
62	IS 18879 (Part 6):2024 ISO 8536-6:2016	Infusion Equipment for Medical Use Part 6 Freeze Drying Closures for Infusion Bottles
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64	IS 18879 (Part 8):2024 ISO 8536-8:2015	Infusion equipment for medical use Part 8 Infusion sets for single use with pressure infusion apparatus
65	IS 18879 (Part 9):2024 ISO 8536-9:2015	Infusion Equipment for Medical Use Part 9 Fluid Lines for Single Use with Pressure Infusion Equipment
66	IS 18879 (Part 10):2024 ISO 8536-10:2015	Infusion Equipment for Medical Use Part 10 Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment
67	IS 18879 (Part 11):2024 ISO 8536-11:2015	Infusion Equipment for Medical Use Part 11 Infusion Filters for Single Use with Pressure Infusion Equipment
68	IS 18879 (Part 12):2024 ISO 8536-12:2021	Infusion Equipment for Medical Use Part 12 Check Valves for Single Use
69	IS 18879 (Part 13):2024 ISO 8536-13:2016	Infusion Equipment for Medical Use Part 13 Graduated Flow Regulators for Single Use with Fluid Contact
70	IS 18879 (Part 14):2024 ISO 8536-14:2016	Infusion Equipment for Medical Use Part 14 Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact
71	IS 18879 (Part 15):2024 ISO 8536-15:2022+Amd1:2023	Infusion Equipment for Medical Use Part 15 Light-Protective Infusion Sets for Single Use
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73	IS 18981:2025	Dialysis Chair
74	IS 19099:2025	Vaccine Carriers General Requirements and Test Methods
75	IS 19106:2025	Refrigerator or Combined Refrigerator and Water-Pack Freezer Intermittent Mains Powered Compression Cycle General Requirements and Test Methods
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86	IS 3119:1978 Reviewed In : 2021	Specification for hot air sterilizers First Revision
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92	IS 3829 (Part 2):1978 Reviewed In : 2021	Specification for steam sterilizers Part 2 horizontal cylindrical high speed steam sterilizers pressure type First Revision
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99	IS 4035:1967 Reviewed In : 2021	Specification for trolleys stretcher
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