

**List of Indian Standards on Important Medical Devices with PPEs, Ventilator, Clinical Thermometer, Thermal Scanner, Wheelchair etc. for use in COVID-19 formulated by Bureau of Indian Standards (BIS)**

S.No.	Product	IS NO. (Any other standard in case Indian Standard not identified)	No. of Licencees *	Details of Testing facility available with BIS or OSL/Govt Lab
1	Ventilators	IS/ISO 80601-2-12 : 2011 'Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	0	Information not available
		IS/ISO 10651-3 : 1997 'Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators	0	Information not available
		IS/ISO 10651-4 : 2002 Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators	0	Information not available
		IS/ISO 10651-5 : 2006 'Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 5: Gas-powered emergency resuscitators	0	Information not available
		IS/ISO 10651-6 : 2004 'Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support	0	Information not available
2	Alcohol based hand rub	Indian Standard/ISO Standard Not available	0	Central Drugs Testing Laboratories
3	Face shield (eye, nose and mouth protection)	IS 8521 (Part 1) : 1977 Specification for industrial safety face shields Part 1 with plastics visor	1	Information not available
4	N95 Masks	IS 9473:2002 (Respiratory protective devices - Filtering half masks to protect against particles)	10	Information not available
5	Latex Single Use Gloves (Clinical)	IS 15354 : PART 1 : 2018 (Single-Use Rubber Examination Gloves)	2	Except Water Tightness & Sterility Test at BIS own laboratory
		IS 13422 : 1992 (Disposable Surgical Rubber Gloves)	26	Complete at 2 BIS own laboratories & Partial (Except Sterility Test) at 2 BIS own laboratories.1 outside laboratory recognized by BIS ( OSL) for the IS.
6	Reusable Vinyl/rubber gloves	IS 4148 : 1989 (Surgical Rubber Gloves)	17	Complete at 4 BIS own laboratories & 4 outside laboratories (OSL) recognized by BIS for the IS
7	Eye Protection (visor/goggles)	IS 5983 : 1980 Specification for eye - Protectors	3	Information not available
8	Protective gowns/aprons	IS 17334:2019 Medical Textiles — Surgical Gowns and Surgical Drapes	0	SITRA, Coimbatore (Partial)
9	Disposable thermometers	(No BIS Standard Available)ASTM E825 - 98(2016) Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature	0	Information not available

10	UV tube light for sterilization	No indian Standard available		Information not available
11	Medical Masks (Surgical/procedure)	IS 16289:2014 (Medical Textiles — Surgical Face Masks)	2	SITRA, Coimbatore as informed over email
12	Detergent/disinfectant	IS 1061:2017 (Disinfectant fluids- Phenolic Type)	45	Complete at 2 BIS own laboratories and partial at 2 BIS own laboratories .7 outside laboratories (OSL) recognized by BIS for the IS
		IS 14364:1996 Quarternary ammonium compound based surface cleaner liquid - Specification	0	Information not available
		IS 10758:1983 Specification for de - odourizing - cum - disinfectant fluids	6	Complete at 1 BIS own laboratory and 2 outside laboratories (OSL) recognized by BIS for the IS
13	Single use towels	No Indian Standard available		Information not available
14	Biohazard bags	No indian Standard available		Information not available
15	Wheel Chair	IS 7454 : 1991 (Rehabilitation equipment - Wheelchairs, folding,adult size)	4	Partial at 1 BIS own laboratory
		IS 8086 : 1991 (Rehabilitation equipment - Wheelchairs, folding, junior size)	1	Partial at 1 BIS own laboratory
16	Glucometer with Strips	IS/ISO 15197 : 2013 In vitro Diagnostic Test Systems — Requirements for Blood-Glucose Monitoring System for Self-Testing in Managing Diabetes Mellitus	0	Information not available
17	Medicine	No Indian Standard available		Information not available
18	IV Fluids - DNS	No Indian Standard available		Information not available
19	IV Fluids - Dextrose	No Indian Standard available		Information not available
20	Hard frozen Gel Packs	No Indian Standard available		Information not available
21	Sample collection kit	No Indian Standard available		Information not available
22	Thermocool box/Ice-box	Indian Standard under formulation MHD12 (13694) Cold box		Information not available
23	Stretcher	IS 4035: 1967 trolleys, stretcher	0	Information not available
		IS 4037 : 1967 STRETCHERS AND STRETCHER CARRIERS	0	Information not available
24	Infrared Thermometer	IS 80601 : Part 2 : Sec 56 : 2017 Medical electrical equipment: Part 2 particular requirements for basic safety and essential performance: Sec 56 clinical thermometers for body temperature measurement	0	Information not available
25	Thermal Scanners	IEC 80601-2-59:2017 Medical electrical equipment — Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	0	Information not available

26	Batteries for thermal scanners	IS 8144 (for non- rechargeable zinc carbon batteries)	9	6 outside laboratories (OSL) recognized by BIS for the IS
		IS 16046 (for rechargeable Nickel and Lithium batteries)	2501	23 outside laboratories (OSL) recognized by BIS for the IS for Year 2015 version, 30 OSLs recognized for Year 2018 part1 and 29 OSL recognized for Year 18 part 2 version Note : Productcovered under the product category 'SEALED SECONDARY CELLS/BATTERIES CONTAININGALKALINE OR OTHER NON-ACID ELECTROLYTES FOR USE IN PORTABLE APPLICATIONS' notified by MeitY
27	BP Apparatus	IS 7652 : 1988 (Sphygmomanometer, Aneroid Type)	3	Complete at 1 and partial at 1 BIS own laboratory
		IS 3390 : 1988 (Sphygmomanometers, Mercurial)	11	Partial at 2 BIS own laboratory
		IS/IEC 80601 : Part 2 : Sec 30 : 2018 Medical electrical equipment: Part 2 - 30 particular requirements for basic safety and essential performance of automated non - Invasive sphygmomanometers	0	Information not available
		IS 13450 ( Part 2 /Sec 34) : 2019 Medical Electrical Equipment Part 2 Particular Requirements for the Basic Safety and Essential Performance Section 34 Invasive blood pressure monitoring equipment	0	Information not available
		IS/ISO 81060 : Part 1 : 2007 Non - Invasive sphygmomanometers: Part 1 requirements and test methods for non - Automated measurement type	0	Information not available
28	IV sets	IS 12655 : Part 4 : 2003,Infusion equipment for medical use: Part 4 infusion sets for single use, gravity feed (First Revision)	0	Information not available
29	IV Cannula	IS 6465 : 1972 Trocar, Antral, with Cannula (Tilley Lichtwitz' Pattern)	0	Information not available
		IS 7981 : Part 2 : 1976 Specification For Instruments. Tuboplasty - Part II : Cannula, Shirodkar's Pattern	0	Information not available
		IS 8313 : 1977 Specification for cannula, flexible, karman type	0	Information not available
		IS 8825 : 1978 Specification for cannula, suction irrigation with locking device, microlaryngeal	0	Information not available
		IS 9911 : 1981 Specification for cannula, brain	0	Information not available
		IS 9984 : 1981 Specification for cannula, air injection, eye	0	Information not available
		IS 10156 : 1982 Specification for cannula, intra - Uterine, hysterosalpingography	0	Information not available
		IS 12270 : 1988 Cannula, Spackmann's Pattern	0	Information not available
		IS 12271 : 1988 Specification for laproscopic trocar and cannula	0	Information not available
30	IV Stand	IS 5880 : 1970 SPECIFICATION FOR STAND, SALINE-CUM-IRRIGATOR	0	Information not available
31	Ambulance	AIS 125(PART2)		Information not available

32	First Aid	IS 13115 : 1991 Portable first -aid kit for general use - Specification	0	Information not available
33	Medical Waste Incinerator	No Indian Standard available		Information not available
34	ICU Beds	IS 9395 : 1979 (Bed, Intensive Care)	1	Information not available
35	Cardiac Monitors	IS 13450(Part 2/Sec 27) : 2018/IEC 60601-2-27 : 2011 Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	0	Information not available
36	Syringe pumps	IS 13450 (Part 2/Sec 24) : 2019/IEC 60601-2-24 : 2012 Medical electrical equipment — Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers (First Revision)	0	Information not available
37	Portable X Ray machines	IS 7620 : PART 1 : 1986 (Diagnostic Medical X-ray Equipment - Part 1 : General and Safety Requirements)	39	Information not available
38	Endotracheal tube	IS 6581 : 1972 Specification for endotracheal tubes (Rubber)	0	Information not available
		IS 6807 : 1972 Reinforced (Flexo-metallic) Magill's Endotracheal Tube	0	Information not available
		IS 8312 : 1977 Forceps, Introducing, Endotracheal Tube, Magill's Pattern	0	Information not available
39	Suction tube	IS 4533 : 1995 (Suction Apparatus)	2	Partial at 1 BIS own laboratory
		IS 9183 : 1979 Suction Tube, Magill's Pattern	0	Information not available
40	Oxygen cylinders	IS 7285 ( Part 1) : 2018 Refillable seamless steel gas cylinders - Specification Part 1 normalized steel cylinders	4	Partial at 1 BIS own laboratory
		7285(Pt 2):2017 Refillable seamless steel gas cylinders – Part 2 Quenched and tempered steel cylinders with tensile Strength less than 1100 MPa (112 kgf/mm2)	7	Partial at 2 BIS own laboratory
		IS 15660 : 2017 Refillable transportable seamless aluminium alloy gas cylinders - Specification	2	Information not available