

## BUREAU OF INDIAN STANDARDS

### Program of Work

#### MHD 6 : Medical and Surgical Cardiology Equipment

**Scope:** 1) To formulate Indian Standards for thoracic and cardiovascular surgery instruments, cardiology equipment, implants and accessories. 2) To coordinate with the work of: a) ISO/TC 150/ SC2 'Cardiovascular Implants & Extracorporeal System': (P Member) b) ISO/TC 150/SC 6 'Active Implants': (P Member) 3) To coordinate the work of sub-committees under this sectional committee (MHD-06): a) Cardiothoracic and Vascular Surgery Sub Committee b) Cardiology Sub Committee

**Liaison:** **ISO TC-150 SC-6 (P): Active implants ISO TC-150 SC-2 (P): Cardiovascular implants and extracorporeal systems**

### Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS 10540 : 1991 <i>Reviewed In : 2022</i>	Cardiovascular Surgery Instruments - Clamps, Atrial Appendage, Glover's Pattern - Shape and Dimensions	April, 2022	-	Indigenous
2	IS 10541 : 1991 <i>Reviewed In : 2022</i>	Cardiovascular surgery instruments - Clamps vena cava, satinsky pattern shape, sizes and dimensions (First Revision)	April, 2022	-	Indigenous
3	IS 11566 : 2024	Thoracic Surgery Instruments " Valve Retractors " Specification (First Revision)		-	Indigenous
4	IS 11566 : 1986 <i>Reviewed In : 2022</i>	Specification for valve retractors	September, 2022	-	Indigenous
5	IS/ISO 11658 : 2012 ISO 11658 : 2012 <i>ISO 11658 : 2012</i>	Cardiovascular Implants and Extracorporeal Organs Blood/Tissue Contact Surface Modifications for Extracorporeal Perfusion Systems		-	Identical under single numbering
6	IS/ISO 12417-1 : 2015 ISO 12417-1 : 2015 <i>IS/ISO 12417-1:2015</i>	Cardiovascular Implants and Extracorporeal Systems Vascular Device-Drug Combination Products Part 1 General Requirements		-	Identical under single numbering
7	IS 13940 : 1994 <i>Reviewed In : 2022</i>	Cardiovascular surgery instruments - Clamps, bulldog, DeBakey, ring handle - Shape and dimensions	April, 2022	-	Indigenous
8	IS/ISO 15674-2004 : 2016 ISO 15674 : 2016 <i>Reviewed In : 2022</i> <i>IS/ISO 15674 : 2016</i>	Cardiovascular implants and artificial organs - Hard - Shell cardiotomy/venous reservoir systems (With/without Filter) and soft venous reservoir bags (Second Revision)	February, 2022	-	Identical under single numbering

9	IS/ISO 15675 : 2016 ISO 15675 : 2016 IS/ISO 15675:2016	Cardiovascular Implants and Artificial Organs Cardiopulmonary Bypass Systems Arterial Blood Line Filters		-	Identical under single numbering
10	IS/ISO 15676 : 2016 ISO 15676 : 2016 ISO 15676 : 2016	Cardiovascular implants and artificial organs Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation ECMO First revision		-	Identical under single numbering
11	IS 17646 (Part 1) : 2021 ISO 23500-1 : 2019 ISO 23500-1 : 2019	Preparation and quality management of fluids for haemodialysis and related therapies : Part 1 General requirements		-	Identical under dual numbering
12	IS 17646 (Part 2) : 2021 IS/ISO 23500-2 : 2019 IS/ISO 23500-2 : 2019	Preparation and quality management of fluids for haemodialysis and related therapies Part 2 Water treatment equipment for haemodialysis applications and related therapies		-	Identical under dual numbering
13	IS 17646 (Part 3) : 2021 ISO 23500-3 : 2019 ISO 23500-3 : 2019	Preparation and quality management of fluids for haemodialysis and related therapies Part 3 Water for haemodialysis and related therapies		-	Identical under dual numbering
14	IS 17646 (Part 4) : 2021 ISO 23500-4 : 2019 ISO 23500-4 : 2019	Preparation and quality management of fluids for haemodialysis and related therapies Part 4 Concentrates for haemodialysis and related therapies		-	Identical under dual numbering
15	IS 17646 (Part 5) : 2021 ISO 23500-5 : 2019 ISO 23500-5 : 2019	Preparation and quality management of fluids for haemodialysis and related therapies Part 5 Quality of dialysis fluid for haemodialysis and related therapies		-	Identical under dual numbering
16	IS 17708 : 2021 ISO/TS 23810:2018 ISO/TS 23810:2018	Cardiovascular implants and artificial organs Checklists for use of extracorporeal circulation equipment		-	Identical under single numbering
17	IS 17709 : 2022 ISO 11318:2002 ISO 11318:2002	Cardiac defibrillators Connector assembly DF-1 for implantable defibrillators Dimensions and test requirements		-	Identical under dual numbering
18	IS 17710 : 2021 ISO 27185:2012 ISO 27185:2012	Cardiac rhythm management devices- Symbols to be used with cardiac rhythm management device labels and information to be supplied General requirements		-	Identical under dual numbering
19	IS 17712 (Part 2) : 2021 ISO 5841-2:2014 ISO 5841-2:2014	Implants for surgery Cardiac pacemakers Part 2: Reporting of clinical performance of populations of pulse generators or leads		-	Identical under dual numbering
20	IS 17712 (Part 3) : 2021 ISO 5841-3:2013 ISO 5841-3:2013	Implants for surgery Cardiac pacemakers Part 3: Low-profile connectors IS-1 for implantable pacemakers		-	Identical under dual numbering
21	IS 17745 : 2021 ISO 5910:2018 ISO 5910:2018	Cardiovascular implants and extracorporeal systems Cardiac valve repair devices		-	Identical under dual numbering

22	IS 17746 : 2021 ISO 27186:2020	Active implantable medical devices Four-pole connector system for implantable cardiac rhythm management devices Dimensional and test requirements		-	Modified/Technically Equivalent
23	IS 17750 (Part 5) : 2021 ISO 14708-5:2020 ISO 14708-5:2020	Implants for surgery Active Implantable Medical Devices Part 5: Circulatory Support Devices		-	Identical under dual numbering
24	IS 17750 (Part 6) : 2022 ISO 14708-6:2019 ISO 14708-6:2019	Implants for Surgery Active Implantable Medical Devices Part 6 Particular Requirements for Active Implantable Medical Devices Intended to Treat Tachyarrhythmia Including Implantable Defibrillators		-	Identical under dual numbering
25	IS 17751 (Part 2) : 2024 ISO/TR 12417-2 ISO/TR 12417-2	Cardiovascular Implants and Extracorporeal Systems $i_c^{1/2}$ Vascular Device-Drug Combination Products Part 2 Local Regulatory Information ( First Revision )		-	Identical under dual numbering
26	IS 17751 : 2022 ISO/TR 12417-2:2017 ISO/TR 12417-2	Cardiovascular implants and extracorporeal systems Vascular device-drug combination products Part 2: Local regulatory information		-	Identical under dual numbering
27	IS 17840 (Part 1) : 2022 5840-1:2021 5840-1:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements		-	Identical under dual numbering
28	IS 17840 (Part 2) : 2022 5840-2:2021 5840-2:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitute First Revision		-	Identical under dual numbering
29	IS 17840 (Part 3) : 2022 ISO 5840-3:2021 ISO 5840-3:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 3 Heart Valve Substitutes Implanted by Transcatheter Techniques First Revision		-	Identical under dual numbering
30	IS 17841 (Part 2) : 2022 ISO 25539:2020 ISO 25539:2020	Cardiovascular Implants Endovascular Devices Part 2 Vascular Stents First Revision		-	Identical under dual numbering
31	IS 17841 (Part 4) : 2023 ISO 25539-4:2021 ISO 25539-4:2021	Cardiovascular Implants Endovascular Devices Part 4 Application of ISO 17327-1 for Coated Endovascular Devices		-	Identical under dual numbering
32	IS 17842 : 2022 ISO 14117:2019 ISO 14117:2019	Active Implantable Medical Devices Electromagnetic Compatibility EMC Test Protocols for Implantable Cardiac Pacemakers Implantable Cardioverter Defibrillators and Cardiac Resynchronization Devices		-	Identical under dual numbering
33	IS 17843 : 2022 ISO/TS 17137:2021 ISO/TS 17137:2021	Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants		-	Identical under dual numbering

34	IS 18207 : 2023 ISO/TR19024:2016 ISO/TR19024:2016	Evaluation of CPB Devices Relative to their Capabilities of Reducing the Transmission of Gaseous Microemboli GME to a Patient during Cardiopulmonary Bypass		-	Identical under dual numbering
35	IS/ISO 18241 : 2016 ISO 18241 : 2016 IS/ISO 18241:2016	Cardiovascular Implants and Extracorporeal Systems Cardiopulmonary Bypass Systems Venous Bubble Traps		-	Identical under single numbering
36	IS/ISO 18242 : 2016 ISO 18242 : 2016 IS/ISO 18242:2016	Cardiovascular Implants and Extracorporeal Systems Centrifugal Blood Pumps		-	Identical under single numbering
37	IS/ISO 25539-1 : 2017 ISO 25539-1 : 2017 ISO 25539 : Part 1	Cardiovascular implants - Endovascular devices: Part 1 endovascular prostheses (First Revision)		-	Identical under single numbering
38	IS/ISO 25539-3 : 2011 ISO 25539-3 : 2011 Reviewed In : 2022 ISO 25539-3 : 2011	Cardiovascular implants - Endovascular devices: Part 3 vena cava filters	February, 2022	-	Identical under single numbering
39	IS 6395 : 2024	Thoracic Surgery Instruments â€” Auricle Clamps, Crafoords Pattern â€” Specification (Second Revision)		-	Indigenous
40	IS 6395 : 1989 Reviewed In : 2022	Thoracic Surgery Instruments - Clamps, Auricle, Crafoord's Pattern	September, 2022	-	Indigenous
41	IS 6436 : 1989 Reviewed In : 2022	Thoracic Surgery Instruments - Rib Spreader, Finochietto's Pattern, Adult Size	September, 2022	-	Indigenous
42	IS 6442 : 2024	Thoracic Surgery Instruments â€” Rib Shears, Tudor Edwardâ€™s Pattern â€” Specification (Second Revision)		-	Indigenous
43	IS 6442 : 1989 Reviewed In : 2023	Thoracic Surgery Instruments - Shears, Rib, Tudor Edward's Pattern for Posterior End of Ribs - Specification(First Revision)	October, 2023	-	Indigenous
44	IS 6466 : 1989 Reviewed In : 2022	Thoracic and cardiovascular surgery instruments - Needle holders - Specification (First Revision)	September, 2022	-	Indigenous
45	IS 6466 : 2024	Thoracic Surgery Instruments â€” Needle Holder â€” Specification		-	Indigenous
46	IS 6467 : 1989 Reviewed In : 2022	Thoracic Surgery Instruments - Periosteotome, Rib, Alexander's Pattern	September, 2022	-	Indigenous
47	IS 6467 : 2024	Thoracic Surgery Instruments â€” Rib Periosteotome, Alexanderâ€™s Pattern â€” Specification (Second Revision)		-	Indigenous
48	IS 6468 : 1989 Reviewed In : 2022	Thoracic Surgery Instruments - Trocar, Empyema, Nelson's Pattern	September, 2022	-	Indigenous
49	IS 6468 : 2024	Thoracic Surgery Instruments â€” Empyema Trocar, Nelsonâ€™s Pattern â€” Specification (Second Revision)		-	Indigenous

50	IS 6777 : 1989 <a href="#">Reviewed In : 2022</a>	Thoracic and cardiovascular surgery instruments - Forceps, dissecting, lung - Specification (First Revision)	September, 2022	-	Indigenous
51	IS 6778 : 1989 <a href="#">Reviewed In : 2022</a>	Thoracic Surgery Instruments - Forceps, Lung, Duval's Pattern	September, 2022	-	Indigenous
52	IS 6778 : 2024	Thoracic Surgery Instruments " Lung Forceps, Duval's Pattern " Specification (Second Revision)		-	Indigenous
53	IS 6779 : 1989 <a href="#">Reviewed In : 2020</a>	Thoracic Surgery Instruments - Forceps, Dissecting and Ligature, Mixer's Pattern - Specification (First Revision)	December, 2020	-	Indigenous
54	IS 6780 : 1989 <a href="#">Reviewed In : 2022</a>	Thoracic Surgery Instruments - Forceps, Artery, Robert's Pattern, Curved on Flat	September, 2022	-	Indigenous
55	IS 6780 : 2024	Thoracic Surgery Instruments " Artery Forceps, Robert's Pattern " Specification (Second Revision)		-	Indigenous
56	IS/ISO 7198 : 2016 ISO 7198 : 2016 <a href="#">IS/ISO 7198:2016</a>	Cardiovascular Implants and Extracorporeal Systems Vascular Prostheses Tubular Vascular Grafts and Vascular Patches		-	Identical under single numbering
57	IS /ISO (Part 7199:1996) : 2016 ISO 7199 : 2016 <a href="#">Reviewed In : 2022</a> <a href="#">ISO 7199 : 2016</a>	Cardiovascular implants and artificial organs - Blood - Gas exchangers (Oxygenators) (Second Revision)	February, 2022	-	Identical under single numbering
58	IS 7345 : 1994 <a href="#">Reviewed In : 2022</a>	Cardiovascular surgery instruments - Anastomosis forceps and clamps - Patterns, shapes and dimensions (Second Revision)	April, 2022	-	Indigenous
59	IS 7346 : 2024	Thoracic Surgery Instruments " Rib Raspatories " Specification (Second Revision)		-	Indigenous
60	IS 7346 : 1987 <a href="#">Reviewed In : 2022</a>	Raspatories, Rib, Semb's Pattern	September, 2022	1	Indigenous
61	IS 7355 : 2024	Thoracic Surgery Instruments " Rib Spreader, Tuffier's Pattern " Specification (Second Revision)		-	Indigenous
62	IS 7355 : 1987 <a href="#">Reviewed In : 2022</a>	Spreader, Rib, Tuffier's Pattern, Adult Size	September, 2022	1	Indigenous
63	IS 7367 : 1987 <a href="#">Reviewed In : 2022</a>	Clamps, Coarctation, Potts' Pattern, Straight and Angular	September, 2022	-	Indigenous
64	IS 7379 : 2024	Thoracic Surgery Instruments " Straight and Angular Patent Ductus Clamps " Specification (Second Revision)		-	Indigenous
65	IS 7379 : 1987 <a href="#">Reviewed In : 2022</a>	Clamps, Patent Ductus, Potts' Pattern, Straight and Angular	September, 2022	-	Indigenous
66	IS 7382 : 2024	Thoracic Surgery Instruments " Rib Shears, Thomas Pattern " Specification (Second Revision)		-	Indigenous
67	IS 7382 : 1987 <a href="#">Reviewed In : 2022</a>	Shears, Rib, Price Thomas' Pattern	September, 2022	-	Indigenous
68	IS 7399 : 1987	Knife, Sternum, Lebsche's Pattern	September, 2022	1	Indigenous

	Reviewed In : 2022				
69	IS 7434 : 1987 Reviewed In : 2022	Retractor, Scapula, Tudor Edward's Pattern	September, 2022	-	Indigenous
70	IS 7434 : 2024	Thoracic Surgery Instruments " Scapula Retractor " Specification (Second Revision)		-	Indigenous
71	IS 7971 : 1987 Reviewed In : 2020	Tourniquet, Cardiovascular Rumel-Belmont's Pattern	January, 2020	-	Indigenous
72	IS 7972 : 2024	Thoracic Surgery Instruments " Dissecting Scissors " Specification (Second Revision)		-	Indigenous
73	IS 7972 : 1987 Reviewed In : 2022	Scissors, Dissecting, Metzenbaum's Pattern	September, 2022	1	Indigenous
74	IS 8317 : 1991 Reviewed In : 2022	Cardiovascular surgery instruments - Clamps, vascular, angled at 45 - Shape and dimensions (First Revision)	April, 2022	-	Indigenous
75	IS 8335 : 1991 Reviewed In : 2022	Cardiovascular Surgery Instruments - Clamps, Auricle, Satinsky Pattern - Sizes, Shape and Dimensions	April, 2022	-	Indigenous
76	IS 8345 : 1994 Reviewed In : 2022	Cardiovascular surgery instruments - Clamps, bulldog, cross action type - Specification (First Revision)	September, 2022	-	Indigenous
77	IS 8549 : 1991 Reviewed In : 2022	Cardiovascular surgery instruments - Angled scissors, potts smith pattern - Specification (First Revision)	September, 2022	-	Indigenous
78	IS 8549 : 2024	Thoracic Surgery Instruments - Angled Scissors - Specification (Second Revision)		-	Indigenous
79	IS/ISO 8637-1 : 2017 ISO 8637-1:2017	Extracorporeal Systems for Blood Purification Part 1 Haemodialysers, Haemodiafilters, Haemofilters and Haemoconcentrators		-	Identical under single numbering
80	IS/ISO 8637-2 : 2018 ISO 8637-2 : 2018 ISO 8637-2:2018	Extracorporeal Systems for Blood Purification Part 2 Extracorporeal Blood Circuit for Haemodialysers, Haemodiafilters and Haemofilters		-	Identical under single numbering
81	IS/ISO 8637-3 : 2018 ISO 5840-3 : 2018 ISO 8637-3:2018	Extracorporeal Systems for Blood Purification Part 3 Plasmafilters		-	Identical under single numbering
82	IS 8890 : 1991 Reviewed In : 2022	Thoracic surgery instruments - Clamps,bronchus - Types, shapes and dimensions (First Revision)	April, 2022	-	Indigenous
83	IS 9928 : 1981 Reviewed In : 2022	Clamp, Aortic, DeBakey's Pattern (Spoon Shaped angled Jaw)	September, 2022	-	Indigenous
84	IS 9950 : 2024	Thoracic Surgery Instruments " Vascular Clamp " Specification (First Revision)		-	Indigenous
85	IS 9950 : 1981 Reviewed In : 2022	Specification for clamp, vascular, wister pattern	September, 2022	-	Indigenous
86	IS 9951 : 2024	Thoracic Surgery Instruments " Blunt End Scissors " Specification (First Revision)		-	Indigenous
87	IS 9951 : 1981	Specification for scissors, blunt	September, 2022	-	Indigenous

	Reviewed In : 2022	end, nelson pattern			
88	IS 9987 : 1981 Reviewed In : 2022	Clamps, Multipurpose, De-bakey's Pattern	September, 2022	-	Indigenous
89	IS 9987 : 2024	Thoracic Surgery Instruments â€”Multipurpose Clamps â€” Specification (First Revision)		-	Indigenous

### Standards under Development

#### Projects Approved

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

#### Preliminary Draft Standards

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

#### Drafts Standards in WC Stage

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

#### Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
1	MHD 6 (24992)	Sizing parameters of surgical valve prostheses Requirements regarding the application of ISO 5840-2
2	MHD 6 (24999)	Cardiovascular implants and artificial organs Cannulae for extracorporeal circulation
3	MHD 6 (25000)	Cardiovascular implants Transcatheter cardiac occluders
4	MHD 6 (25002)	Implants for surgery Active implantable medical devices Part 4 Implantable infusion pump systems

#### Finalized Draft Indian Standard

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

#### Finalized Draft Indian Standards under Print

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

**Total Published Standards:70 Total Standards Under development:4**

### Aspect Wise Report

Product : 59  
Code of Practices : 8  
Methods of Test : 3  
Terminology : 0  
Dimensions : 0  
System Standard : 0  
Safety Standard : 0  
Others : 0  
Service Specification : 0

**Annexure-I :List of Indian Standards Withdrawn/Superseded**

SI. No.	IS No. & Year	Title
1	IS 13878 : 1993 ISO 8638 Reviewed In : 2010	Extra Corporeal Circuit For Haemodialysers Haemofilters And Haemoconcentrators
2	IS 13890 : 1994 ISO 8637 Reviewed In : 2010	Haemodialysers Haemofilters and Haemoconcentrators
3	IS 13924 : 1994 ISO 5840 Reviewed In : 2010	Cardiovascular Implants - Cardiac Valve - Prosthesis
4	IS/ISO 13958 : 2014 ISO 13958 : 2014 ISO 13958 : 2014	Concentrates for Haemodialysis and Related Therapies
5	IS/ISO 13959 : 2014 ISO 13959 : 2014 ISO 13959 : 2014	Water for haemodialysis and related therapies
6	IS/ISO 13960 : 2010 ISO 13960 : 2010 ISO 13960 : 2010	Cardiovascular implants and extracorporeal systems - Plasmafilters First Revision
7	IS/ISO/TS 15539 : 2000 ISO/TS 15539:2000 Reviewed In : 2017	Cardiovascular Implants -- Endovascular Prosthesis
8	IS/ISO 23500 : 2014 ISO 23500 : 2014 ISO 23500 : 2014	Guidance for the preparation and quality management of fluids for haemodialysis and related therapies
9	IS/ISO 25539-2 : 2012 ISO 25539-2 : 2012 Reviewed In : 2022 25539	Cardiovascular implants - Endovascular devices Part 2 vascular stents
10	IS/ISO 5840 : 2005 ISO 5840 Reviewed In : 2016	Cardiovascular implants - Cardiac valve prostheses
11	IS/ISO 5840-2 : 2015 ISO 5840-2 : 2015	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitutes
12	IS/ISO 5840-3 : 2013 ISO 5840-3 : 2013 ISO 5840-3 : 2013	Cardiovascular Implants Cardiac Valve Prostheses Part 3 Heart Valve Substitutes Implanted by Trans-Catheter Techniques
13	IS 8409 : 1991 Reviewed In : 2021	Cardiovascular Surgery Instruments - Dilator Valve Tubbs Mitral Pattern
14	IS 8550 : 1977 Reviewed In : 2001	Scissors angled on flat Potts Smith pattern
15	IS/ISO 8637-2004 : 2010 ISO 8637:2010 ISO 8637:2010	Cardiovascular implants and extracorporeal systems - Haemodialysers haemodiafilters haemofilters and haemoconcentrators First Revision
16	IS/ISO 8638-2004 : 2010 ISO 8638 : 2010 ISO 8638 : 2010	Cardiovascular implants and extracorporeal systems - Extracorporeal blood circuit for haemodialysers haemodiafilters and haemofilters First Revision
17	IS 8898 : 1978	Clamp anastomosis Cooley s pattern
18	IS 9927 : 1981	Clamp anastomosis dale-femoral Popliteal s pattern

**Annexure-II :List of Indian Product Standards**



SI. No.	IS No. & Year	Title
1	IS 10540 : 1991 Reviewed In : 2022	Cardiovascular Surgery Instruments - Clamps Atrial Appendage Glover s Pattern - Shape and Dimensions
2	IS 10541 : 1991 Reviewed In : 2022	Cardiovascular surgery instruments - Clamps vena cava satinsky pattern shape sizes and dimensions First Revision
3	IS 11566 : 2024	Thoracic Surgery Instruments Valve Retractors Specification First Revision
4	IS/ISO 12417-1 : 2015 ISO 12417-1 : 2015 IS/ISO 12417-1:2015	Cardiovascular Implants and Extracorporeal Systems Vascular Device-Drug Combination Products Part 1 General Requirements
5	IS 13940 : 1994 Reviewed In : 2022	Cardiovascular surgery instruments - Clamps bulldog DeBakey ring handle - Shape and dimensions
6	IS/ISO 15674-2004 : 2016 ISO 15674 : 2016 Reviewed In : 2022 IS/ISO 15674 : 2016	Cardiovascular implants and artificial organs - Hard - Shell cardiotomy venous reservoir systems With without Filter and soft venous reservoir bags Second Revision
7	IS/ISO 15675 : 2016 ISO 15675 : 2016 IS/ISO 15675:2016	Cardiovascular Implants and Artificial Organs Cardiopulmonary Bypass Systems Arterial Blood Line Filters
8	IS/ISO 15676 : 2016 ISO 15676 : 2016 ISO 10555-6:2015	Cardiovascular implants and artificial organs Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation ECMO First revision
9	IS 17709 : 2022 ISO 11318:2002 ISO 5744 : 2004	Cardiac defibrillators Connector assembly DF-1 for implantable defibrillators Dimensions and test requirements
10	IS 17712 (Part 3) : 2021 ISO 5841-3:2013	Implants for surgery Cardiac pacemakers Part 3 Low-profile connectors IS-1 for implantable pacemakers
11	IS 17745 : 2021 ISO 5910:2018 ISO 9008:1991	Cardiovascular implants and extracorporeal systems Cardiac valve repair devices
12	IS 17746 : 2021 ISO/IEC 17629:2014	Active implantable medical devices Four-pole connector system for implantable cardiac rhythm management devices Dimensional and test requirements
13	IS 17750 (Part 5) : 2021 ISO 14708-5:2020 ISO/IEC 23736-6: 2020	Implants for surgery Active Implantable Medical Devices Part 5 Circulatory Support Devices
14	IS 17750 (Part 6) : 2022 ISO 14708-6:2019 ISO/IEC 7942-3: 1999	Implants for Surgery Active Implantable Medical Devices Part 6 Particular Requirements for Active Implantable Medical Devices Intended to Treat Tachyarrhythmia Including Implantable Defibrillators
15	IS 17751 (Part 2) : 2024 ISO/TR 12417-2	Cardiovascular Implants and Extracorporeal Systems Vascular Device-Drug Combination Products Part 2 Local Regulatory Information First Revision
16	IS 17840 (Part 1) : 2022 5840-1:2021 ISO 8362-1:2018	Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements
17	IS 17840 (Part 2) : 2022 5840-2:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitute First Revision
18	IS 17840 (Part 3) : 2022 ISO 5840-3:2021 ISO 9276-3 :2008	Cardiovascular Implants Cardiac Valve Prostheses Part 3 Heart Valve Substitutes Implanted by Transcatheter Techniques First Revision
19	IS 17841 (Part 2) : 2022 ISO 25539:2020 ISO 14344:2010	Cardiovascular Implants Endovascular Devices Part 2 Vascular Stents First Revision
20	IS 17841 (Part 4) : 2023 ISO 25539-4:2021	Cardiovascular Implants Endovascular Devices Part 4 Application of ISO 17327-1 for Coated Endovascular Devices
21	IS 17843 : 2022	Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants

	ISO/TS 17137:2021 ISO 12749-1 : 2020	
22	IS/ISO 18241 : 2016 ISO 18241 : 2016 IS/ISO 18241:2016	Cardiovascular Implants and Extracorporeal Systems Cardiopulmonary Bypass Systems Venous Bubble Traps
23	IS/ISO 18242 : 2016 ISO 18242 : 2016 IS/ISO 18242:2016	Cardiovascular Implants and Extracorporeal Systems Centrifugal Blood Pumps
24	IS/ISO 25539-1 : 2017 ISO 25539-1 : 2017 ISO 25539 : Part 1	Cardiovascular implants - Endovascular devices Part 1 endovascular prostheses First Revision
25	IS/ISO 25539-3 : 2011 ISO 25539-3 : 2011 Reviewed In : 2022 ISO 25539-3 : 2011	Cardiovascular implants - Endovascular devices Part 3 vena cava filters
26	IS 6395 : 2024	Thoracic Surgery Instruments Auricle Clamps Crafoords Pattern Specification Second Revision
27	IS 6436 : 1989 Reviewed In : 2022	Thoracic Surgery Instruments - Rib Spreader Finochietto s Pattern Adult Size
28	IS 6442 : 2024	Thoracic Surgery Instruments Rib Shears Tudor Edward s Pattern Specification Second Revision
29	IS 6466 : 2024	Thoracic Surgery Instruments Needle Holder Specification
30	IS 6467 : 2024	Thoracic Surgery Instruments Rib Periosteotome Alexander s Pattern Specification Second Revision
31	IS 6468 : 2024	Thoracic Surgery Instruments Empyema Trocar Nelson s Pattern Specification Second Revision
32	IS 6777 : 1989 Reviewed In : 2022	Thoracic and cardiovascular surgery instruments - Forceps dissecting lung - Specification First Revision
33	IS 6778 : 2024	Thoracic Surgery Instruments Lung Forceps Duval s Pattern Specification Second Revision
34	IS 6779 : 1989 Reviewed In : 2020	Thoracic Surgery Instruments - Forceps Dissecting and Ligature Mixer 39 s Pattern - Specification First Revision
35	IS 6780 : 2024	Thoracic Surgery Instruments Artery Forceps Robert s Pattern Specification Second Revision
36	IS/ISO 7198 : 2016 ISO 7198 : 2016 IS/ISO 7198:2016	Cardiovascular Implants and Extracorporeal Systems Vascular Prostheses Tubular Vascular Grafts and Vascular Patches
37	IS /ISO (Part 71991996) : 2016 ISO 7199 : 2016 Reviewed In : 2022 ISO 7199 : 2016	Cardiovascular implants and artificial organs - Blood - Gas exchangers Oxygenators Second Revision
38	IS 7345 : 1994 Reviewed In : 2022	Cardiovascular surgery instruments - Anastomosis forceps and clamps - Patterns shapes and dimensions Second Revision
39	IS 7346 : 2024	Thoracic Surgery Instruments Rib Raspatories Specification Second Revision
40	IS 7355 : 2024	Thoracic Surgery Instruments Rib Spreader Tuffier s Pattern Specification Second Revision
41	IS 7367 : 1987 Reviewed In : 2022	Clamps Coarctation Potts Pattern Straight and Angular
42	IS 7379 : 2024	Thoracic Surgery Instruments Straight and Angular Patent Ductus Clamps Specification Second Revision
43	IS 7382 : 2024	Thoracic Surgery Instruments Rib Shears Thomas Pattern Specification Second Revision
44	IS 7399 : 1987 Reviewed In : 2022	Knife Sternum Lebsche s Pattern
45	IS 7434 : 2024	Thoracic Surgery Instruments Scapula Retractor Specification Second Revision

46	IS 7971 : 1987 Reviewed In : 2020	Tourniquet Cardiovascular Rumel-Belmont s Pattern
47	IS 7972 : 2024	Thoracic Surgery Instruments Dissecting Scissors Specification Second Revision
48	IS 8317 : 1991 Reviewed In : 2022	Cardiovascular surgery instruments - Clamps vascular angled at 45 - Shape and dimensions First Revision
49	IS 8335 : 1991 Reviewed In : 2022	Cardiovascular Surgery Instruments - Clamps Auricle Satinsky Pattern - Sizes Shape and Dimensions
50	IS 8345 : 1994 Reviewed In : 2022	Cardiovascular surgery instruments - Clamps bulldog cross action type - Specification First Revision
51	IS 8549 : 2024	Thoracic Surgery Instruments - Angled Scissors - Specification Second Revision
52	IS/ISO 8637-1 : 2017 ISO 8637-1:2017	Extracorporeal Systems for Blood Purification Part 1 Haemodialysers Haemodiafilters Haemofilters and Haemoconcentrators
53	IS/ISO 8637-2 : 2018 ISO 8637-2 : 2018 ISO 8637-2:2018	Extracorporeal Systems for Blood Purification Part 2 Extracorporeal Blood Circuit for Haemodialysers Haemodiafilters and Haemofilters
54	IS/ISO 8637-3 : 2018 ISO 5840-3 : 2018 ISO 8637-3:2018	Extracorporeal Systems for Blood Purification Part 3 Plasmafilters
55	IS 8890 : 1991 Reviewed In : 2022	Thoracic surgery instruments - Clamps bronchus - Types shapes and dimensions First Revision
56	IS 9928 : 1981 Reviewed In : 2022	Clamp Aortic DeBakey s Pattern Spoon Shaped angled Jaw
57	IS 9950 : 2024	Thoracic Surgery Instruments Vascular Clamp Specification First Revision
58	IS 9951 : 2024	Thoracic Surgery Instruments Blunt End Scissors Specification First Revision
59	IS 9987 : 2024	Thoracic Surgery Instruments Multipurpose Clamps Specification First Revision