

## 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 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	Cardiovascular Surgery Instruments - Clamps, Atrial Appendage, Glover's Pattern - Shape and Dimensions	April, 2022	-	Indigenous
2	IS 10541:1991	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/ISO 11658:2012 ISO 11658 : 2012 ISO 11658 : 2012	Cardiovascular Implants and Extracorporeal Organs Blood/Tissue Contact Surface Modifications for Extracorporeal Perfusion Systems		-	Identical under single numbering
5	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		-	Identical under single numbering
6	IS 13940:1994	Cardiovascular surgery instruments - Clamps, bulldog, DeBakey, ring handle - Shape and dimensions	April, 2022	-	Indigenous
7	IS/ISO 15674-2004:2016 ISO 15674 : 2016 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)	February, 2022	-	Identical under single numbering
8	IS/ISO 15675:2016	Cardiovascular Implants and		-	Identical under single

	ISO 15675 : 2016 IS/ISO 15675:2016	Artificial Organs Cardiopulmonary Bypass Systems Arterial Blood Line Filters			numbering
9	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
10	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
11	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
12	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
13	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
14	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
15	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
16	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
17	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
18	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
19	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
20	IS 17745:2021 ISO 5910:2018 ISO 5910:2018	Cardiovascular implants and extracorporeal systems Cardiac valve repair devices		-	Identical under dual numbering
21	IS 17746:2021	Active implantable medical devices		-	Modified/Technically

	ISO 27186:2020	Four-pole connector system for implantable cardiac rhythm management devices Dimensional and test requirements			Equivalent
22	IS 17750 (Part 4):2025 ISO 14708-4:2022	Implants for surgery i <sub>c</sub> ½ Active implantable medical devices i <sub>c</sub> ½ Part 4: Implantable infusion pump systems (ISO 14708-4 : 2022, MOD)		-	Modified/Technically Equivalent
23	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
24	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
25	IS 17751 (Part 2):2024 ISO/TR 12417-2 ISO/TR 12417-2	Cardiovascular Implants and Extracorporeal Systems i <sub>c</sub> ½ Vascular Device-Drug Combination Products Part 2 Local Regulatory Information ( First Revision )		-	Identical under dual numbering
26	IS 17840 (Part 1):2022 5840-1:2021 5840-1:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements		-	Identical under dual numbering
27	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
28	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
29	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
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 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
32	IS 17843:2022 ISO/TS 17137:2021 ISO/TS 17137:2021	Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants		-	Identical under dual numbering
33	IS 18207:2023	Evaluation of CPB Devices		-	Identical under dual

	ISO/TR19024:2016 ISO/TR19024:2016	Relative to their Capabilities of Reducing the Transmission of Gaseous Microemboli GME to a Patient during Cardiopulmonary Bypass			numbering
34	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
35	IS/ISO 18242:2016 ISO 18242 : 2016 IS/ISO 18242:2016	Cardiovascular Implants and Extracorporeal Systems Centrifugal Blood Pumps		-	Identical under single numbering
36	IS 18903:2025 ISO/PAS 7020:2023 ISO/PAS 7020:2023	Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2		-	Identical under dual numbering
37	IS 18927:2024 ISO 22679:2021	Cardiovascular implants $\frac{1}{2}$ Transcatheter cardiac occluders (ISO 22679 : 2021, MOD)		-	Modified/Technically Equivalent
38	IS 18974:2025 ISO 18193:2021	Cardiovascular Implants and Artificial Organs $\frac{1}{2}$ Cannulae for Extracorporeal Circulation (ISO 18193 : 2021, MOD)		-	Modified/Technically Equivalent
39	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
40	IS/ISO 25539-3:2011 ISO 25539-3 : 2011 ISO 25539-3 : 2011	Cardiovascular implants - Endovascular devices: Part 3 vena cava filters	February, 2022	-	Identical under single numbering
41	IS 6395:2024	Thoracic Surgery Instruments $\hat{\text{e}}$ Auricle Clamps, Crafoords Pattern $\hat{\text{e}}$ Specification (Second Revision)		-	Indigenous
42	IS 6436:1989	Thoracic Surgery Instruments - Rib Spreader, Finochietto's Pattern, Adult Size	September, 2022	-	Indigenous
43	IS 6442:2024	Thoracic Surgery Instruments $\hat{\text{e}}$ Rib Shears, Tudor Edward $\hat{\text{e}}$ Pattern $\hat{\text{e}}$ Specification (Second Revision)		-	Indigenous
44	IS 6466:2024	Thoracic Surgery Instruments $\hat{\text{e}}$ Needle Holder $\hat{\text{e}}$ Specification		-	Indigenous
45	IS 6467:2024	Thoracic Surgery Instruments $\hat{\text{e}}$ Rib Periosteotome, Alexander $\hat{\text{e}}$ Pattern $\hat{\text{e}}$ Specification (Second Revision)		-	Indigenous
46	IS 6468:2024	Thoracic Surgery Instruments $\hat{\text{e}}$ Empyema Trocar, Nelson $\hat{\text{e}}$ Pattern $\hat{\text{e}}$ Specification (Second Revision)		-	Indigenous
47	IS 6777:1989	Thoracic and cardiovascular surgery instruments - Forceps, dissecting, lung - Specification (First Revision)	September, 2022	-	Indigenous
48	IS 6778:2024	Thoracic Surgery Instruments $\hat{\text{e}}$ Lung Forceps, Duval $\hat{\text{e}}$ Pattern $\hat{\text{e}}$ Specification (Second Revision)		-	Indigenous

49	IS 6780:2024	Thoracic Surgery Instruments â€” Artery Forceps, Robertâ€™s Pattern â€” Specification (Second Revision)		-	Indigenous
50	IS/ISO 7198:2016 ISO 7198 : 2016 IS/ISO 7198:2016	Cardiovascular Implants and Extracorporeal Systems Vascular Prostheses Tubular Vascular Grafts and Vascular Patches		-	Identical under single numbering
51	IS 7199 (Part 71991996):2016 ISO 7199 : 2016 ISO 7199 : 2016	Cardiovascular implants and artificial organs - Blood - Gas exchangers (Oxygenators) (Second Revision)	February, 2022	-	Identical under single numbering
52	IS 7345:1994	Cardiovascular surgery instruments - Anastomosis forceps and clamps - Patterns, shapes and dimensions (Second Revision)	April, 2022	-	Indigenous
53	IS 7346:2024	Thoracic Surgery Instruments â€” Rib Raspatories â€” Specification (Second Revision)		-	Indigenous
54	IS 7355:2024	Thoracic Surgery Instruments â€” Rib Spreader, Tuffierâ€™s Pattern â€” Specification (Second Revision)		-	Indigenous
55	IS 7367:1987	Clamps, Coarctation, Potts' Pattern, Straight and Angular	September, 2022	-	Indigenous
56	IS 7379:2024	Thoracic Surgery Instruments â€” Straight and Angular Patent Ductus Clamps â€” Specification (Second Revision)		-	Indigenous
57	IS 7382:2024	Thoracic Surgery Instruments â€” Rib Shears, Thomas Pattern â€” Specification (Second Revision)		-	Indigenous
58	IS 7399:1987	Knife, Sternum, Lebsche's Pattern	September, 2022	1	Indigenous
59	IS 7434:2024	Thoracic Surgery Instruments â€” Scapula Retractor â€” Specification (Second Revision)		-	Indigenous
60	IS 7972:2024	Thoracic Surgery Instruments â€” Dissecting Scissors â€” Specification (Second Revision)		-	Indigenous
61	IS 8317:1991	Cardiovascular surgery instruments - Clamps, vascular, angled at 45 - Shape and dimensions (First Revision)	April, 2022	-	Indigenous
62	IS 8335:1991	Cardiovascular Surgery Instruments - Clamps, Auricle, Satinsky Pattern - Sizes, Shape and Dimensions	April, 2022	-	Indigenous
63	IS 8345:1994	Cardiovascular surgery instruments - Clamps, bulldog, cross action type - Specification (First Revision)	September, 2022	-	Indigenous
64	IS 8549:2024	Thoracic Surgery Instruments - Angled Scissors - Specification (Second Revision)		-	Indigenous
65	IS/ISO 8637-1:2017 ISO 8637-1:2017	Extracorporeal Systems for Blood Purification Part 1 Haemodialysers, Haemodiafilters, Haemofilters and		-	Identical under single numbering

Haemoconcentrators					
66	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
67	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
68	IS 8890:1991	Thoracic surgery instruments - Clamps,bronchus - Types, shapes and dimensions (First Revision)	April, 2022	-	Indigenous
69	IS 9928:1981	Clamp, Aortic, DeBakey's Pattern (Spoon Shaped angled Jaw)	September, 2022	-	Indigenous
70	IS 9950:2024	Thoracic Surgery Instruments "Vascular Clamp" Specification (First Revision)		-	Indigenous
71	IS 9951:2024	Thoracic Surgery Instruments "Blunt End Scissors" Specification (First Revision)		-	Indigenous
72	IS 9987:2024	Thoracic Surgery Instruments "Multipurpose Clamps" 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
1	MHD 6 (27693)	Medical Cardiology Instruments Intracardiac Sucker - Specifications
2	MHD 6 (28470)	Dialyzer Reprocessing Machines 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 6 (26591) <span style="color: green;">Revision of: IS 10540:1991</span>	Thoracic Surgery Instruments - Atrial Appendage Clamps Glovers Pattern - Specification
2	MHD 6 (26592) <span style="color: green;">Revision of: IS 10541:1991</span>	Thoracic Surgery Instruments - Vena cava Clamps Satinskys pattern - Specification
3	MHD 6 (26594) <span style="color: green;">Revision of: IS 7345:1994</span>	Thoracic Surgery Instruments - Anastomosis forceps and Clamps - Specification
4	MHD 6 (26596) <span style="color: green;">Revision of: IS 8335:1991</span>	Thoracic Surgery Instruments - Auricle Clamps - Specification
		Thoracic Surgery Instruments -Bronchus Clamps - Specification

5	MHD 6 (26597) Revision of: IS 8890:1991	
6	MHD 6 (26608) Revision of: IS 6777:1989	Thoracic Surgery Instruments - Dissecting Forceps for lungs - Specification
7	MHD 6 (26610) Revision of: IS 7367:1987	Thoracic Surgery Instruments - Straight and Angular Coarctation Clamps Potts Pattern - Specification
8	MHD 6 (26611) Revision of: IS 7399:1987	Thoracic Surgery Instruments - Sternum Knife Lebsches Pattern - Specification
9	MHD 6 (26612) Revision of: IS 9928:1981	Thoracic Surgery Instruments - Aortic Clamp DeBakeys Pattern - Specification

### Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
1	MHD 6 (00211)	CARDIOVASCULAR IMPLANTS AND ARTIFICIAL ORGANS - REQUIREMENTS FOR SINGLE-USE TUBING PACKS FOR CARDIOPULMONARY BYPASS AND EXTRACORPOREAL MEMBRANE OXYGENATION ECMO
2	MHD 6 (00213) Revision of: IS 7199:2016	CARDIOVASCULAR IMPLANTS AND ARTIFICIAL ORGANS --- BLOOD-GAS EXCHANGERS OXYGENATORS First Revision
3	MHD 6 (00214) Revision of: IS/ISO 8637:2010	Cardiovascular Implants and extracorporeal systems --- Haemodialysers Haemodiafilters Haemofilters and Haemoconcentrators First Revision
4	MHD 6 (00215) Revision of: IS/ISO 8638:2010	CARDIOVASCULAR IMPLANTS AND EXTRACORPOREAL SYSTEMS -- EXTRACORPOREAL BLOOD CIRCUIT FOR HAEMODIALYSERS HAEMODIAFILTERS AND HAEMOFILTERS First Revision
5	MHD 6 (00217) Revision of: IS/ISO 15674:2016	CARDIOVASCULAR IMPLANTS AND ARTIFICIAL ORGANS - HARD-SHELL CARDIOTOMY VENOUS RESERVOIR SYSTEMS WITH WITHOUT FILTER AND SOFT VENOUS RESERVOIR BAGS First Revision
6	MHD 6 (00216) Revision of: IS/ISO 13960:2010	CARDIOVASCULAR IMPLANTS AND EXTRACORPOREAL SYSTEMS - PLASMAFILTERS First Revision
7	MHD 6 (10382)	CARDIOVASCULAR IMPLANTS ---ENDOASCULAR DEVICES PART 2 VASCULAR STENTS
8	MHD 6 (10383)	CARDIOVASCULAR IMPLANTS ---ENDOASCULAR DEVICES PART 3 VENA CAVA FILTERS
9	MHD 6 (11596) Revision of: IS 7199:2016	Cardiovascular implants and artificial organs Blood-gas exchangers oxygenators Second Revision
10	MHD 6 (11598) Revision of: IS/ISO 15674:2016	Cardiovascular implants and artificial organs Hard-shell cardiotomyvenous reservoir systems withwithout filter and soft venous reservoir bags Second Revision
11	MHD 6 (12971)	Cardiovascular implants and artificial organs Bloodtissue contact surface modifications for extracorporeal perfusion system
12	MHD 6 (12972)	Concentrates for haemodialysis and related therapies
13	MHD 6 (12973)	Water for haemodialysis and related therapies
14	MHD 6 (12974) Revision of: IS/ISO 15676:2005	Cardiovascular implants and artificial organs Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation ECMO First revision
15	MHD 6 (12975)	Guidance for the preparation and quality management of fluids for haemodialysis and related therapies
16	MHD 6 (13122)	Cardiovascular implants and extracorporeal systems Vascular prostheses Tubular vascular grafts and vascular patches
17	MHD 6 (13124)	Cardiovascular implants and extracorporeal systems Vascular Device-drug combination products Part 1 General requirements
18	MHD 6 (13125)	Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial blood line filters
19	MHD 6 (13126)	Cardiovascular implants and extracorporeal systems Cardiopulmonary bypass systems Venous bubble traps
20	MHD 6 (13127)	Cardiovascular implants and extracorporeal systems Centrifugal blood pumps
21	MHD 6 (13128) Revision of: IS/ISO 25539:2017	Cardiovascular implants - Endovascular devices - Part 1 Endovascular prostheses
22	MHD 6 (13462)	Cardiovascular implants -- Cardiac valve prostheses -- Part 2 Surgically implanted heart valve substitutes
23	MHD 6 (13463)	Cardiovascular implants Cardiac valve prostheses Part 3 Heart valve substitutes implanted by

		Trans-catheter techniques
24	MHD 6 (14326)	Extracorporeal systems for blood purification - Part 1 Haemodialysers haemodiafilters haemofilters and haemoconcentrators
25	MHD 6 (14327)	Extracorporeal systems for blood purification - Part 2 Extracorporeal blood circuit for haemodialysers haemodiafilters and haemofilters
26	MHD 6 (14328)	Extracorporeal systems for blood purification - Part 3 Plasmafilters
27	MHD 6 (15598)	Preparation and quality management of fluids for haemodialysis and related therapies Part 1 General requirements
28	MHD 6 (15599)	Preparation and quality management of fluids for haemodialysis and related therapies Part 2 Water treatment equipment for haemodialysis applications and related therapies
29	MHD 6 (15600)	Preparation and quality management of fluids for haemodialysis and related therapies Part 3 Water for haemodialysis and related therapies
30	MHD 6 (15601)	Preparation and quality management of fluids for haemodialysis and related therapies Part 4 Concentrates for haemodialysis and related therapies
31	MHD 6 (15602)	Preparation and quality management of fluids for haemodialysis and related therapies Part 5 Quality of dialysis fluid for haemodialysis and related therapies
32	MHD 6 (15780)	Cardiovascular implants and extracorporeal systems Cardiac valve repair devices
33	MHD 6 (17400)	Cardiovascular implants and extracorporeal systems Vascular device-drug combination products Part 2 Local regulatory information
34	MHD 6 (17401)	Cardiovascular implants and artificial organs Checklists for use of extracorporeal circulation equipment
35	MHD 6 (17403)	Implants for surgery Cardiac pacemakers Part 2 Reporting of clinical performance of populations of pulse generators or leads
36	MHD 6 (17404)	Implants for surgery Cardiac pacemakers Part 3 Low-profile connectors IS-1 for implantable pacemakers
37	MHD 6 (17406)	Cardiac defibrillators Connector assembly DF-1 for implantable defibrillators Dimensions and test requirements
38	MHD 6 (17407)	Cardiac rhythm management devices- Symbols to be used with cardiac rhythm management device labels and information to be supplied General requirements
39	MHD 6 (17409)	Active implantable medical devices Four-pole connector system for implantable cardiac rhythm management devices Dimensional and test requirements
40	MHD 6 (17438)	Implants for surgery Active Implantable Medical Devices Part 5 Circulatory Support Devices
41	MHD 6 (18158)	Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements
42	MHD 6 (18159) Revision of: IS/ISO 5840:2015	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitute First Revision
43	MHD 6 (18160) Revision of: IS/ISO 5840:2013	Cardiovascular Implants Cardiac Valve Prostheses Part 3 Heart Valve Substitutes Implanted by Transcatheter Techniques First Revision
44	MHD 6 (18161) Revision of: IS/ISO 25539:2012	Cardiovascular Implants Endovascular Devices Part 2 Vascular Stents First Revision
45	MHD 6 (18162)	Evaluation of CPB Devices Relative to their Capabilities of Reducing the Transmission of Gaseous Microemboli GME to a Patient during Cardiopulmonary Bypass
46	MHD 6 (18163)	Active Implantable Medical Devices Electromagnetic Compatibility EMC Test Protocols for Implantable Cardiac Pacemakers Implantable Cardioverter Defibrillators and Cardiac Resynchronization Devices
47	MHD 6 (18164)	Implants for Surgery Active Implantable Medical Devices Part 6 Particular Requirements for Active Implantable Medical Devices Intended to Treat Tachyarrhythmia Including Implantable Defibrillators
48	MHD 6 (18165)	Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants
49	MHD 6 (20911) Revision of: IS 7346:1987	Thoracic Surgery Instruments - Rib Raspatories - Specification
50	MHD 6 (20912) Revision of: IS 6395:1989	Thoracic Surgery Instruments - Auricle Clamps - Crafoords Pattern - Specification Second Revision
51	MHD 6 (20914) Revision of: IS 6442:1989	Thoracic Surgery Instruments - Rib Shears Tudor Edward s pattern - Specification Second Revision
52	MHD 6 (20915) Revision of: IS 6466:1989	Thoracic Surgery Instruments - Needle Holder - Specification Second Revision
53	MHD 6 (20916) Revision of: IS 6467:1989	Thoracic Surgery Instruments Periosteotome Rib Alexanders Pattern Specification Second Revision
54	MHD 6 (20917) Revision	Thoracic Surgery Instruments - Empyema Trocar Nelson s Pattern - Specification Second

	of: IS 6468:1989	Revision
55	MHD 6 (20920) Revision of: IS 6778:1989	Thoracic Surgery Instruments - Lung Forceps Duval s Pattern - Specification Second Revision
56	MHD 6 (20921) Revision of: IS 6780:1989	Thoracic Surgery Instruments - Artery Forceps Robert s Pattern - Specification Second Revision
57	MHD 6 (20922) Revision of: IS 7355:1987	Specification for Spreader Rib Tuffiers Pattern Adult Size Second Revision
58	MHD 6 (20924) Revision of: IS 7379:1987	Thoracic Surgery Instruments - Straight and Angular Patent Ductus Clamps - Specification Second Revision
59	MHD 6 (20925) Revision of: IS 7382:1987	Thoracic Surgery Instruments - Rib Shears Thomas Pattern - Specification Second Revision
60	MHD 6 (20927) Revision of: IS 7434:1987	Thoracic Surgery Instruments - Scapula Retractor - Specification Second Revision
61	MHD 6 (20928) Revision of: IS 7972:1987	Thoracic Surgery Instruments - Dissecting Scissors - Specification Second Revision
62	MHD 6 (20930) Revision of: IS 8549:1991	Thoracic Surgery Instruments - Angled Scissors - Specification Second Revision
63	MHD 6 (20932) Revision of: IS 9950:1981	Thoracic Surgery Instruments - Vascular Clamp - Specification First Revision
64	MHD 6 (20933) Revision of: IS 9951:1981	Thoracic Surgery Instruments - Blunt End Scissors - Specification First Revision
65	MHD 6 (20934) Revision of: IS 9987:1981	Thoracic Surgery Instruments - Multipurpose Clamps - Specification First Revision
66	MHD 6 (20935) Revision of: IS 11566:1986	Specification for Valve Retractors First Revision
67	MHD 6 (21272)	Cardiovascular Implants Endovascular Devices Part 4 Application of ISO 17327-1 for Coated Endovascular Devices
68	MHD 6 (23653) Revision of: IS 17751:2022	Cardiovascular Implants and Extracorporeal Systems Vascular Device-Drug Combination Products Part 2 Local Regulatory Information First Revision
69	MHD 6 (24992)	Sizing parameters of surgical valve prostheses Requirements regarding the application of ISO 5840-2
70	MHD 6 (24999)	Cardiovascular Implants and Artificial Organs Cannulae for Extracorporeal Circulation ISO 18193 2021 MOD
71	MHD 6 (25000)	Cardiovascular implants Transcatheter cardiac occluders ISO 22679 2021 MOD
72	MHD 6 (25002)	Implants for surgery Active implantable medical devices Part 4 Implantable infusion pump systems ISO 14708-4 2022 MOD
73	MHD 6 (26577) Revision of: IS 8345:1994	Thoracic Surgery Instruments Bulldog Clamps Specification
74	MHD 6 (26588) Revision of: IS 6436:1989	Thoracic Surgery Instruments Rib Spreader Finochietto s Pattern Adult Size Specification
75	MHD 6 (26593) Revision of: IS 13940:1994	Cardiovascular Surgery Instruments Bulldog Clamp DeBaKey Pattern Specification First Revision
76	MHD 6 (26595) Revision of: IS 8317:1991	Cardiovascular Surgery Instruments Angled Vascular Clamps Specification

**Total Published Standards:72 Total Standards Under development:87**

### Aspect Wise Report

Product : 61  
Code of Practices : 7  
Methods of Test : 3  
Terminology : 0  
Dimensions : 1  
System Standard : 0  
Safety Standard : 0  
Others : 0  
Service Specification : 0  
Process Specification : 0

<b>Annexure-I :List of Indian Standards Withdrawn/Superseded</b>
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Sl. 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 - Prostheses
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 Prostheses
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 25539	Cardiovascular implants - Endovascular devices Part 2 vascular stents
10	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
11	IS/ISO 5840:2005 ISO 5840 Reviewed In : 2016	Cardiovascular implants - Cardiac valve prostheses
12	IS/ISO 5840-2:2015 ISO 5840-2 : 2015	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitutes
13	IS 6779:1989	Thoracic Surgery Instruments - Forceps Dissecting and Ligature Mixer 39 s Pattern - Specification First Revision
14	IS 7971:1987	Tourniquet Cardiovascular Rumel-Belmont s Pattern
15	IS 8409:1991 Reviewed In : 2021	Cardiovascular Surgery Instruments - Dilator Valve Tub s Mitral Pattern
16	IS 8550:1977 Reviewed In : 2001	Scissors angled on flat Potts Smith pattern
17	IS/ISO 8637-2004:2010 ISO 8637:2010 ISO 8637:2010	Cardiovascular implants and extracorporeal systems - Haemodialysers haemodiafilters haemofilters and haemoconcentrators First Revision
18	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
19	IS 8898:1978	Clamp anastomosis Cooley s pattern
20	IS 9927:1981	Clamp anastomosis dale-femoral Popliteal s pattern

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

<b>Sl. No.</b>	<b>IS No. &amp; Year</b>	<b>Title</b>
1	IS 10540:1991	Cardiovascular Surgery Instruments - Clamps Atrial Appendage Glover s Pattern - Shape and Dimensions
2	IS 10541:1991	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	Cardiovascular surgery instruments - Clamps bulldog DeBaKey ring handle - Shape and dimensions
6	IS/ISO 15674-2004:2016 ISO 15674 : 2016 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 17646 (Part 2):2021 IS/ISO 23500-2 : 2019 ISO/TR 22696:2020	Preparation and quality management of fluids for haemodialysis and related therapies Part 2 Water treatment equipment for haemodialysis applications and related therapies
10	IS 17709:2022 ISO 11318:2002 ISO 5744 : 2004	Cardiac defibrillators Connector assembly DF-1 for implantable defibrillators Dimensions and test requirements
11	IS 17712 (Part 3):2021 ISO 5841-3:2013	Implants for surgery Cardiac pacemakers Part 3 Low-profile connectors IS-1 for implantable pacemakers
12	IS 17745:2021 ISO 5910:2018 ISO 9008:1991	Cardiovascular implants and extracorporeal systems Cardiac valve repair devices
13	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
14	IS 17750 (Part 4):2025	Implants for surgery Active implantable medical devices Part 4 Implantable infusion pump systems ISO 14708-4 2022 MOD
15	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
16	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
17	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
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 17840 (Part 2):2022 5840-2:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitute First Revision
20	IS 17840 (Part 1):2022 5840-1:2021 ISO 8362-1:2018	Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements
21	IS 17841 (Part 4):2023	Cardiovascular Implants Endovascular Devices Part 4 Application of ISO 17327-1 for Coated

	ISO 25539-4:2021 ISO 16457 : 2022	Endovascular Devices
22	IS 17841 (Part 2):2022 ISO 25539:2020 ISO 14344:2010	Cardiovascular Implants Endovascular Devices Part 2 Vascular Stents First Revision
23	IS 17843:2022 ISO/TS 17137:2021 ISO 12749-1 : 2020	Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants
24	IS/ISO 18241:2016 ISO 18241 : 2016 IS/ISO 18241:2016	Cardiovascular Implants and Extracorporeal Systems Cardiopulmonary Bypass Systems Venous Bubble Traps
25	IS/ISO 18242:2016 ISO 18242 : 2016 IS/ISO 18242:2016	Cardiovascular Implants and Extracorporeal Systems Centrifugal Blood Pumps
26	IS 18927:2024	Cardiovascular implants Transcatheter cardiac occluders ISO 22679 2021 MOD
27	IS 18974:2025	Cardiovascular Implants and Artificial Organs Cannulae for Extracorporeal Circulation ISO 18193 2021 MOD
28	IS/ISO 25539-3:2011 ISO 25539-3 : 2011 ISO 25539-3 : 2011	Cardiovascular implants - Endovascular devices Part 3 vena cava filters
29	IS/ISO 25539-1:2017 ISO 25539-1 : 2017 ISO 25539 : Part 1	Cardiovascular implants - Endovascular devices Part 1 endovascular prostheses First Revision
30	IS 6395:2024	Thoracic Surgery Instruments Auricle Clamps Crafoords Pattern Specification Second Revision
31	IS 6436:1989	Thoracic Surgery Instruments - Rib Spreader Finochietto s Pattern Adult Size
32	IS 6442:2024	Thoracic Surgery Instruments Rib Shears Tudor Edward s Pattern Specification Second Revision
33	IS 6466:2024	Thoracic Surgery Instruments Needle Holder Specification
34	IS 6467:2024	Thoracic Surgery Instruments Rib Periosteotome Alexander s Pattern Specification Second Revision
35	IS 6468:2024	Thoracic Surgery Instruments Empyema Trocar Nelson s Pattern Specification Second Revision
36	IS 6777:1989	Thoracic and cardiovascular surgery instruments - Forceps dissecting lung - Specification First Revision
37	IS 6778:2024	Thoracic Surgery Instruments Lung Forceps Duval s Pattern Specification Second Revision
38	IS 6780:2024	Thoracic Surgery Instruments Artery Forceps Robert s Pattern Specification Second Revision
39	IS/ISO 7198:2016 ISO 7198 : 2016 IS/ISO 7198:2016	Cardiovascular Implants and Extracorporeal Systems Vascular Prostheses Tubular Vascular Grafts and Vascular Patches
40	IS 7199 (Part 71991996):2016 ISO 7199 : 2016 ISO 7199 : 2016	Cardiovascular implants and artificial organs - Blood - Gas exchangers Oxygenators Second Revision
41	IS 7345:1994	Cardiovascular surgery instruments - Anastomosis forceps and clamps - Patterns shapes and dimensions Second Revision
42	IS 7346:2024	Thoracic Surgery Instruments Rib Raspatories Specification Second Revision
43	IS 7355:2024	Thoracic Surgery Instruments Rib Spreader Tuffier s Pattern Specification Second Revision
44	IS 7367:1987	Clamps Coarctation Potts Pattern Straight and Angular
45	IS 7379:2024	Thoracic Surgery Instruments Straight and Angular Patent Ductus Clamps Specification Second Revision

46	IS 7382:2024	Thoracic Surgery Instruments Rib Shears Thomas Pattern Specification Second Revision
47	IS 7399:1987	Knife Sternum Lebsche s Pattern
48	IS 7434:2024	Thoracic Surgery Instruments Scapula Retractor Specification Second Revision
49	IS 7972:2024	Thoracic Surgery Instruments Dissecting Scissors Specification Second Revision
50	IS 8317:1991	Cardiovascular surgery instruments - Clamps vascular angled at 45 - Shape and dimensions First Revision
51	IS 8335:1991	Cardiovascular Surgery Instruments - Clamps Auricle Satinsky Pattern - Sizes Shape and Dimensions
52	IS 8345:1994	Cardiovascular surgery instruments - Clamps bulldog cross action type - Specification First Revision
53	IS 8549:2024	Thoracic Surgery Instruments - Angled Scissors - Specification Second Revision
54	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
55	IS/ISO 8637-1:2017 ISO 8637-1:2017	Extracorporeal Systems for Blood Purification Part 1 Haemodialysers Haemodiafilters Haemofilters and Haemoconcentrators
56	IS/ISO 8637-3:2018 ISO 5840-3 : 2018 ISO 8637-3:2018	Extracorporeal Systems for Blood Purification Part 3 Plasmafilters
57	IS 8890:1991	Thoracic surgery instruments - Clamps bronchus - Types shapes and dimensions First Revision
58	IS 9928:1981	Clamp Aortic DeBakey s Pattern Spoon Shaped angled Jaw
59	IS 9950:2024	Thoracic Surgery Instruments Vascular Clamp Specification First Revision
60	IS 9951:2024	Thoracic Surgery Instruments Blunt End Scissors Specification First Revision
61	IS 9987:2024	Thoracic Surgery Instruments Multipurpose Clamps Specification First Revision