

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
BUREAU OF INDIAN STANDARDS

AGENDA

Meeting	Day & Date	Time
14th meeting of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06 [via WebEx platform]	Wednesday, 02-August-2023	12 PM
Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m42c376611ae25efabf1668e19d28a8f0 Meeting number: 2518 026 7307 Password: MHD06@14		

Chairperson: Dr. Deepak Kumar Satsangi (In personal Capacity)

Member Secretary: Mr. Pawan Kumar, Scientist-B, MHD, BIS, New Delhi

ITEM 0 GENERAL

0.1 WELCOME BY MEMBER SECRETARY

0.2 OPENING REMARKS BY THE CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The minutes of the previous (Thirteenth) meeting of the Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06, held online through video conferencing on 16th December, 2022 duly approved by the Chairperson, were circulated to all the members vide letter no. MHD/06/A-2.13 dated 2nd January, 2023. No comments were received regarding the accuracy of recording of decision taken by the Committee in the meeting.

The Committee may formally confirm the minutes.

ITEM 2 PROCESS REFORMS IN STANDARDIZATION ACTIVITY OF BIS

2.1 Presentation on process reforms in standardization activity of BIS has been attached as Annex-1.

2.2 Annual Meeting Calendar

As per guidelines, every Sectional Committee is required to meet once per quarter (Wherever work items are available). In this regard, each committee needs to prepare the annual meeting calendar in the beginning of every financial year. The draft Annual Meeting Calendar for the consideration of Medical and Surgical Cardiology Equipment Sectional Committee is as given below.

Quarter	Q2 July-Sept 2023	Q3 Oct-Dec 2023	Q4 Jan-Mar 2024
Date	2nd Aug 2023, Wednesday	7th December 2023, Thursday	20th February 2024, Tuesday

Committee may deliberate and decide.

ITEM 3 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

3.1 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’: (O 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

The Committee may please note and review the scope.

3.2 COMPOSITION OF SECTIONAL COMMITTEE

The present composition of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06 is given in [Annex-2](#) (Page 6-9).

General BIS guidelines related to Composition:

- a) Consumer interests shall, as far as possible, predominate. In case non industry interests are less than two third, it may be reviewed to ensure that 2/3rd of the total representation on the committee is from non-industry.
- b) Only relevant organizations/government departments/consumer organizations/regulatory bodies that are related to the subject may be offered representation.
- c) The organizations representing for reasonably long time (more than six years) without participation/contribution may be substituted by new organizations that are capable of contributing in the new technologies/areas of the work.

ITEM 4 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

The following Draft Indian Standards / amendments are currently under wide circulation:

S.No	Document No./Title	Last Date of Comments
1.	MHD/06/20911 Specification for Raspatories Rib Sembs Pattern Second Revision	27 th June, 2023
2.	MHD/06/20912 Thoracic Surgery Instruments Clamps Auricle Crafoords Pattern Specification Second Revision	27 th June, 2023
3.	MHD/06/20913 Thoracic Surgery Instruments Rib Spreader Finochiettos Pattern Adult Size Specification Second Revision	27 th June, 2023
4.	MHD/06/20914 Thoracic Surgery Instruments Shears Rib Tudor Edwards Pattern For Posterior End of Ribs Specification Second Revision	27 th June, 2023
5.	MHD/06/20915 Thoracic Surgery Instruments Needle Holder Specification Second Revision	27 th June, 2023

6.	MHD/06/20916 Thoracic Surgery Instruments Periosteotome Rib Alexanders Pattern Specification Second Revision	27 th June, 2023
7.	MHD/06/20917 Thoracic Surgery Instruments Trocar Empyema Nelsons Pattern Specification Second Revision	27 th June, 2023
8.	MHD/06/20919 Thoracic and Cardiovascular Surgery Instruments Forceps Dissecting Lung Specification Second Revision	27 th June, 2023
9.	MHD/06/20920 Thoracic Surgery Instruments Forceps Lung Duvals Pattern Specification Second Revision	27 th June, 2023
10.	MHD/06/20921 Thoracic Surgery Instruments Forceps Artery Roberts Pattern Curved on Flat - Specification Second Revision	27 th June, 2023
11.	MHD/06/20922 Specification for Spreader Rib Tuffiers Pattern Adult Size Second Revision	27 th June, 2023
12.	MHD/06/20923 Specification for Clamps Coarctation Potts Pattern Straight and Angular Second Revision	27 th June, 2023
13.	MHD/06/20924 Specification for Clamps Patent Ductus Potts Pattern Straight and Angular Second Revision	27 th June, 2023
14.	MHD/06/20925 Specification for Shears Rib Price Thomas Pattern Second Revision	27 th June, 2023
15.	MHD/06/20926 Specification for Knife Sternum Lebsches Pattern Second Revision	27 th June, 2023
16.	MHD/06/20927 Specification for Retractor Scapula Tudor Edwards Pattern Second Revision	27 th June, 2023
17.	MHD/06/20928 Specification for Scissors Dissecting Metzenbaums Pattern Second Revision	27 th June, 2023
18.	MHD/06/20929 Cardiovascular Surgery Instruments Clamps Bulldog Cross Action Type Specification Second Revision	27 th June, 2023
19.	MHD/06/20930 Cardiovascular Surgery Instruments Angled Scissors Potts Smith Pattern Specification Second Revision	27 th June, 2023
20.	MHD/06/20931 Specification for Clamp Aortic DeBakeys Pattern Spoon Shaped Angled Jaw First Revision	27 th June, 2023
21.	MHD/06/20932 Specification for Clamp Vascular Wister Pattern First Revision	27 th June, 2023
22.	MHD/06/20933 Specification for Scissors Blunt End Nelson Pattern First Revision	27 th June, 2023
23.	MHD/06/20934 Specification for Clamps Multipurpose DeBakeys Pattern First Revision	27 th June, 2023
24.	MHD/06/20935 Specification for Valve Retractors First Revision	27 th June, 2023

The committee may please note.

ITEM 5 DRAFT STANDARDS / AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

S. No	ISO No.	Title
1.	ISO/TR 12417-2:2022	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 2: Local regulatory information

The Committee may please deliberate and decide further course of action.

ITEM 6 DRAFTS UNDER PREPARATION

- Electric operated sternum saw system
- Battery operated sternum saw system
- Rotablation Machine

The Committee may deliberate and decide further course of action.

ITEM 7 COMMENTS ON PUBLISHED STANDARD

There are no comments on published standard.

The committee may please note.

ITEM 8 NEW SUBJECTS

There are no new subjects in the committee.

ITEM 9 INTERNATIONAL ACTIVITIES

India's Participation Status in ISO Technical Committees/Subcommittees.

- I) ISO/TC 150/SC 2 'Cardiovascular Implants & Extracorporeal Systems': (P member)
- II) ISO/TC 150/SC 6 'Active Implants' (O Member)

The ISO Standards published under ISO/TC/150/SC2 along with their status of adoption is given in [Annex-3](#) (Page 10-11).

The Committee may please examine and identify the ISO Standard(s) which may be adopted as Indian Standard(s), keeping in view India's National interest.

- As a P-member, it is mandatory to vote on all draft standards and other documents circulated by ISO seeking votes/comments. It is reiterated that the members should carefully examine the documents taking into consideration nation's interests and send their comments keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation.
- The committee may also deliberate and discuss on obtaining P-membership in ISO/TC 150/SC 6.

The Committee may please note

ITEM 10 PROGRAMME OF WORK (INCLUDING PERIODIC REVIEW OF INDIAN STANDARDS)

10.1 The present programme of work of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06 is provided in [Annex-4](#) (Page 12-15)

The Committee may please note.

10.2 Review of Indian Standards published before year 2000

All the Indian Standards formulated under MHD 06 before 2000 may be reviewed for revision/withdrawal in the light of technological developments that have happened so far in relation to these standards.

The list of Indian Standard under MHD 06 which are published prior to year 2000 is given at [Annex-5](#) (Page 16-17).

The committee may please note and decide further course of action

ITEM 11 DATE AND PLACE OF NEXT MEETING

ITEM 12 ANY OTHER BUSINESS

ANNEX 2

COMPOSITION OF SECTIONAL COMMITTEE

S. No.	Organization	Member Name	Role	Attendance (Last 3 meeting)
1.	In Personal Capacity	Dr. Deepak Kumar Satsangi	Chairperson	3/3
2.	All India Institute of Medical Sciences, New Delhi	Dr. Milind P Hote	Principal Member	1/3
3.	All India Institute of Medical Sciences, New Delhi	Dr. Pradeep Ramakrishna Reddy	Alternate Member	0/2
4.	Apollo Hospital, Chennai	Dr. C. S. Vijayshankar	Principal Member	0/3
5.	Apollo Hospital, Chennai	Dr. T. Sunder	Alternate Member	0/3
6.	B.L Lifesciences Private Limited, New Delhi	Ms. Nonita Kawatra	Principal Member	0/3
7.	B.L Lifesciences Private Limited, New Delhi	Shri Hemant Kumar Singh	Alternate Member	0/3
8.	B.L Lifesciences Private Limited, New Delhi	Ms. Priyanka Sachan	Young Professional	0/3
9.	Birla Institute of Technology and Science, Pilani	Dr. Pawan Ajmera	Principal Member	0/3
10.	Birla Institute of Technology and Science, Pilani	Dr. Sujan Yenuganti	Alternate Member	0/3
11.	Boston Scientific India Private Limited, Gurugram	Shri Prashanth Prabhakar	Principal Member	1/2
12.	Boston Scientific India Private Limited, Gurugram	Shri Dev Chopra	Alternate Member	1/2
13.	CSIR-Central Scientific Instruments Organisation, Chandigarh	Shri Neelesh Kumar	Principal Member	0/3
14.	CSIR-Central Scientific Instruments Organisation, Chandigarh	Dr. Sanjeev Soni	Alternate Member	0/3
15.	Cardinal Health Medical Products India Private Limited, Mumbai	Shri Saurobh Poddar	Principal Member	-
16.	Central Drugs Standard Control Organization, New Delhi	Dr. Ravi Kant Sharma	Alternate Member	1/3
17.	Christian Medical College, Vellore	Shri Ravi Shankar	Principal Member	0/3
18.	Christian Medical College, Vellore	Dr. Shalom Sylvester Andugala	Alternate Member	0/3
19.	Directorate General Armed Forces Medical Service, New Delhi	Col Sameer Kumar	Principal Member	0/3

20.	Directorate General Armed Forces Medical Service, New Delhi	Col Paul M Varghese	Alternate Member	0/3
21.	Dnyandeo Yashwantrao Patil Hospital, Navi Mumbai	Dr. James Thomas	Principal Member	0/3
22.	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Vijay Kumar Gupta	Principal Member	0/3
23.	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Vijay Grover	Alternate Member	0/3
24.	Frontier Lifeline Private Limited, Chennai	Dr. Sanjay Cherian	Principal Member	0/3
25.	Frontier Lifeline Private Limited, Chennai	Dr. Kulasekaran	Alternate Member	0/3
26.	Hindalco Industries Limited, Mumbai	Shri K. Venkatesh	Principal Member	0/3
27.	Institute for Cardiac Treatment and Research, Delhi	Dr. R. Jaganathan	Principal Member	0/3
28.	Institute for Cardiac Treatment and Research, Delhi	Dr. N. R. Ravi Shankar	Alternate Member	0/3
29.	India Medtronic Private Limited, Gurugram	Ms Latika Vats	Principal Member	0/3
30.	India Medtronic Private Limited, Gurugram	Shri Sanjeev Minhas	Alternate Member	0/3
31.	Indian Association of Cardiovascular - Thoracic Surgeons, Bengaluru	Dr. C S Hiremath	Principal Member	0/2
32.	Indian Association of Cardiovascular - Thoracic Surgeons, Bengaluru	Dr. Shamsher Singh Lohchab	Alternate Member	1/2
33.	Indian Heart Foundation, Hyderabad	Dr. Sishir Rao	Principal Member	0/3
34.	Indian Heart Foundation, Hyderabad	Dr. Sevith Rao	Alternate Member	0/3
35.	Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry	Shri Durga Prasad Rath	Principal Member	1/ 3
36.	Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry	Shri Ramsankar P	Alternate Member	2/3
37.	Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry	Shri Hemachandren M	Young Professional	1/3
38.	Johnson and Johnson Private Limited, Mumbai	Shri Yateen Shah	Principal Member	0/3
39.	Johnson and Johnson Private Limited, Mumbai	Shri Aaditya Vats	Alternate Member	0/1

40.	Johnson and Johnson Private Limited, Mumbai	Shri Gautham A	Young Professional	1/1
41.	Kalam Institute of Health Technology, Vishakhapatnam	Dr. Jitendar Sharma	Principal Member	0/3
42.	Kalam Institute of Health Technology, Vishakhapatnam	Shri Dilip Kumar Chekuri	Alternate Member	0/3
43.	Kalam Institute of Health Technology, Vishakhapatnam	Shri Kiran Kumar P	Young Professional	1/3
44.	Meril Life Sciences Private Limited, Vapi	Shri Narendra Patel	Principal Member	1/3
45.	Meril Life Sciences Private Limited, Vapi	Ms Gayathri Nair	Alternate Member	2/3
46.	Meril Life Sciences Private Limited, Vapi	Shri Mohmed Hashim	Young Professional	3/3
47.	Ministry of Electronics and Information Technology, New Delhi	Smt Sunita Verma	Principal Member	0/3
48.	Ministry of Electronics and Information Technology, New Delhi	Shri Rashid Shaban	Alternate Member	1/3
49.	Nizam's Institute of Medical Sciences, Hyderabad	Prof. R. V Kumar	Principal Member	0/3
50.	Nizam's Institute of Medical Sciences, Hyderabad	Dr. M. Amaresh Rao	Alternate Member	0/3
51.	North-Eastern Hill University, Shillong	Dr. Sudip Paul	Principal Member	1/3
52.	North-Eastern Hill University, Shillong	Shri Shyamal Mandal	Alternate Member	0/3
53.	Office of Development Commissioner (MSME), New Delhi	Shri Sunil Kumar	Principal Member	1/2
54.	Office of Development Commissioner (MSME), New Delhi	Shri Susanta Kumar Som	Alternate Member	1/2
55.	Post Graduate Institute of Medical Education and Research, Chandigarh	Prof Harkant Singh	Principal Member	0/3
56.	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Anand K Mishra	Alternate Member	0/3
57.	South India Surgical Company Limited(SISCO), Chennai	Shri Ashok Bajaj	Principal Member	0/3
58.	South India Surgical Company Limited(SISCO), Chennai	Shri Bharat Bhushan	Alternate Member	0/3
59.	Sree Chitra Tirunal Institute for Medical Sciences &	Prof. Vivek V. Pillai	Principal Member	1/3

	Technology, Thiruvananthapuram			
60.	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Prof. Bineesh K.R.	Alternate Member	0/3
61.	Stryker India Private Limited, Gurugram	Shri Shivkumar Hurdale	Alternate Member	0/3
62.	TTK Healthcare Limited (Heart Valve), Chennai	Shri Rajiv K. Nair	Principal Member	1/3
63.	TTK Healthcare Limited (Heart Valve), Chennai	Ms. Indu V Nair	Alternate Member	3/3

ANNEX 3

STANDARDS PUBLISHED BY ISO TC 150/SC2

Cardiovascular implants and extracorporeal systems

S.No	ISO No.	Title	Status
1.	ISO 18193:2021	Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation	Not Adopted
2.	ISO/TR 12417-2:2022	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 2: Local regulatory information	(To be Revised) 2017 version is adopted
3.	ISO 22679:2021	Cardiovascular implants — Transcatheter cardiac occluders	Not Adopted
4.	ISO 5840-1:2021	Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements	Published
5.	ISO 5840-2:2021	Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes	Published
6.	ISO 5840-3:2021	Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques	Published
7.	ISO 25539-2:2020	Cardiovascular implants — Endovascular devices — Part 2: Vascular stents	Published
8.	ISO/TS 17137:2021	Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants	Published
9.	ISO/TR 19024:2016	Evaluation of CPB devices relative to their capabilities of reducing the transmission of gaseous microemboli (GME) to a patient during cardiopulmonary bypass	Published
10.	ISO 23500-1:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements	Published
11.	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	Published
12.	ISO 23500-3:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies	Published
13.	ISO 23500-4:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies	Published
14.	ISO 23500-5:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 5:	Published

		Quality of dialysis fluid for haemodialysis and related therapies	
15.	ISO 5910:2018	Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices	Published
16.	ISO/TS 23810:2018	Cardiovascular implants and artificial organs — Checklists for use of extracorporeal circulation equipment	Published
17.	ISO 7198:2016	Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches	Adopted
18.	ISO 7199:2016	Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)	Adopted
19.	ISO 8637-1:2017	Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	Adopted
20.	ISO 8637-2:2018	Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters	Adopted
21.	ISO 8637-3:2018	Extracorporeal systems for blood purification — Part 3: Plasmafilters	Adopted
22.	ISO 11658:2012	Cardiovascular implants and extracorporeal systems — Blood/tissue contact surface modifications for extracorporeal perfusion systems	Adopted
23.	ISO 12417-1:2015	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements	Adopted
24.	ISO 15676:2016	Cardiovascular implants and artificial organs — Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)	Adopted
25.	ISO 18242:2016	Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps	Adopted
26.	ISO 25539-1:2017	Cardiovascular implants — Endovascular devices — Part 1: Endovascular prostheses	Adopted
27.	ISO 25539-3:2011	Cardiovascular implants — Endovascular devices — Part 3: Vena cava filters	Adopted

ANNEX 4
PROGRAMME OF WORK

S.No	IS No.	Title
1.	IS 17840 (Part 1): 2022 5840-1:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 1 General Requirements
2.	IS 17840 (Part 2):2022/ISO 5840-2:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 2 Surgically Implanted Heart Valve Substitutes
3.	IS 17840(Part 3):2022/ISO 5840-3:2021	Cardiovascular Implants Cardiac Valve Prostheses Part 3 Heart Valve Substitutes Implanted by Trans- Catheter Techniques
4.	IS 17841 (Part 2): 2022 ISO 25539:2020	Cardiovascular Implants Endovascular Devices Part 2 Vascular Stents First Revision
5.	IS 17842: 2022 ISO 14117:2019	Active Implantable Medical Devices Electromagnetic Compatibility EMC Test Protocols for Implantable Cardiac Pacemakers Implantable Cardioverter Defibrillators and Cardiac Resynchronization Devices
6.	IS 17843: 2022 ISO/TS 17137:2021	Cardiovascular Implants and Extracorporeal Systems Cardiovascular Absorbable Implants
7.	IS 17750 (Part 6): 2022 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
8.	IS 17751 (Part 2): 2022 ISO/TR 12417-2:2017	Cardiovascular implants and extracorporeal systems Vascular device-drug combination products Part 2 Local regulatory information
9.	IS/ISO 7198 : 2016	Cardiovascular Implants and Extracorporeal Systems Vascular Prostheses Tubular Vascular Grafts and Vascular Patches
10.	IS/ISO 7199 : 2016	Cardiovascular implants and artificial organs - Blood - Gas exchangers Oxygenators Second Revision
11.	IS/ISO 8637 : Part 1 : 2017	Extracorporeal Systems for Blood Purification Part 1 Haemodialysers Haemodiafilters Haemofilters and Haemoconcentrators
12.	IS/ISO 8637 : Part 2 : 2018	Extracorporeal Systems for Blood Purification Part 2 Extracorporeal Blood Circuit for Haemodialysers Haemodiafilters and Haemofilters
13.	IS/ISO 8637 : Part 3 : 2018	Extracorporeal Systems for Blood Purification Part 3 Plasmafilters
14.	IS/ISO 11658 : 2012	Cardiovascular Implants and Extracorporeal Organs Blood Tissue Contact Surface Modifications for Extracorporeal Perfusion Systems
15.	IS/ISO 12417 : Part 1 : 2015	Cardiovascular Implants and Extracorporeal Systems Vascular Device-Drug Combination Products Part 1 General Requirements

16.	IS/ISO 15674 : 2016	Cardiovascular implants and artificial organs - Hard - Shell cardiotomy venous reservoir systems With and without Filter and soft venous reservoir bags Second Revision
17.	IS/ISO 15675 : 2016	Cardiovascular Implants and Artificial Organs Cardiopulmonary Bypass Systems Arterial Blood Line Filters
18.	IS/ISO 18241 : 2016	Cardiovascular Implants and Extracorporeal Systems Cardiopulmonary Bypass Systems Venous Bubble Traps
19.	IS/ISO 18242 : 2016	Cardiovascular Implants and Extracorporeal Systems Centrifugal Blood Pumps
20.	IS/ISO 25539 : Part 1 : 2017	Cardiovascular implants - Endovascular devices Part 1 endovascular prostheses First Revision
21.	IS/ISO 25539 : Part 3 : 2011	Cardiovascular implants - Endovascular devices Part 3 vena cava filters
22.	IS 17646(Part 1):2021/ ISO 23500-1:2019	Preparation and quality management of fluids for haemodialysis and related therapies Part 1 General requirements
23.	IS 17646(Part 2):2021 /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
24.	IS 17646(Part 3):2021/ ISO 23500-3:2019)	Preparation and quality management of fluids for haemodialysis and related therapies Part 3 Water for haemodialysis and related therapies
25.	IS 17646(Part 4):2021/ISO 23500-4:2019)	Preparation and quality management of fluids for haemodialysis and related therapies Part 4 Concentrates for haemodialysis and related therapies
26.	IS 17646(Part 5):2021/ 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
27.	IS 17708 : 2021/ ISO/TS 23810:2018	Cardiovascular implants and artificial organs Checklists for use of extracorporeal circulation equipment
28.	IS 17710: 2021 ISO 27185:2012	Cardiac rhythm management devices- Symbols to be used with cardiac rhythm management device labels and information to be supplied General requirements
29.	IS 17712 (Part 2) : 2021/ ISO 5841-2:2014	Implants for surgery Cardiac pacemakers Part 2 Reporting of clinical performance of populations of pulse generators or leads
30.	IS 17712 (Part 3) : 2021 ISO 5841-3:2013	Implants for surgery Cardiac pacemakers Part 3 Low-profile connectors IS-1 for implantable pacemakers
31.	IS 17745: 2021 ISO 5910:2018	Cardiovascular implants and extracorporeal systems Cardiac valve repair devices
32.	IS 17746 : 2021	Active implantable medical devices Four-pole connector system for implantable cardiac rhythm

		management devices Dimensional and test requirements
33.	IS 17750 (Part 5): 2021 ISO 14708-5:2020	Implants for surgery Active Implantable Medical Devices Part 5 Circulatory Support Devices
34.	IS 9928 : 1981	Clamp Aortic DeBakey s Pattern Spoon Shaped angled Jaw
35.	IS 9950 : 1981	Clamp Vascular Wister Pattern
36.	IS 9951 : 1981	Scissors Blunt End Nelson Pattern
37.	IS 9987 : 1981	Clamps Multipurpose De-bakey s Pattern
38.	IS 6395 : 1989	Thoracic Surgery Instruments - Clamps Auricle Crafoord s Pattern
39.	IS 6436 : 1989	Thoracic Surgery Instruments - Rib Spreader Finochietto s Pattern Adult Size
40.	IS 6442 : 1989	Thoracic Surgery Instruments - Shears Rib Tudor Edward s Pattern for Posterior End of Ribs
41.	IS 7346 : 1987	Raspatories Rib Semb s Pattern
42.	IS 7355 : 1987	Spreader Rib Tuffier s Pattern Adult Size
43.	IS 7367 : 1987	Clamps Coarctation Potts Pattern Straight and Angular
44.	IS 7379 : 1987	Clamps Patent Ductus Potts Pattern Straight and Angular
45.	IS 7382 : 1987	Shears Rib Price Thomas Pattern
46.	IS 7972 : 1987	Scissors Dissecting Metzenbaum s Pattern
47.	IS 11566 :1986	Valve Retractors
48.	IS 6466 : 1989	Thoracic and Cardiovascular Surgery Instruments - Needle Holders
49.	IS 6467 : 1989	Thoracic Surgery Instruments - Periosteotome Rib Alexander s Pattern
50.	IS 6468 : 1989	Thoracic Surgery Instruments - Trocar Empyema Nelson s Pattern
51.	IS 6777 : 1989	Thoracic and Cardiovascular Surgery Instruments - Forceps Dissecting Lung
52.	IS 6778 : 1989	Thoracic Surgery Instruments - Forceps Lung Duval s Pattern
53.	IS 6779 : 1989	Thoracic Surgery Instruments - Forceps Dissecting and Ligature Mixer s Pattern
54.	IS 6780 : 1989	Thoracic Surgery Instruments - Forceps Artery Robert s Pattern Curved on Flat
55.	IS 7345 : 1994	Cardiovascular Surgery Instruments - Anastomosis Forceps and Clamps - Patterns Shapes and Dimensions
56.	IS 7399 : 1987	Knife Sternum Lebsche s Pattern
57.	IS 7434 : 1987	Retractor Scapula Tudor Edward s Pattern
58.	IS 7971 : 1987	Tourniquet Cardiovascular Rumel-Belmont s Pattern
59.	IS 8317 : 1991	Cardiovascular Surgery Instruments - Clamps Vascular Angled at 45 - Shape and Dimensions
60.	IS 8335 : 1991	Cardiovascular Surgery Instruments - Clamps Auricle Satinsky Pattern - Sizes Shape and Dimensions

61.	IS 8345 : 1994	Cardiovascular surgery instruments - Clamps bulldog cross action type
62.	IS 8549 : 1991	Cardiovascular Surgery Instruments - Angled Scissors Potts Smith Pattern
63.	IS 8890 : 1991	Thoracic Surgery Instruments - Clamps Bronchus - Types Shapes and Dimensions
64.	IS 10540 : 1991	Cardiovascular Surgery Instruments - Clamps Atrial Appendage Glover s Pattern - Shape and Dimensions
65.	IS 13940 : 1994	Cardiovascular Surgery Instruments - Clamps Bulldog DeBakey Ring Handle - Shape and Dimensions

ANNEX 5

INDIAN STANDARDS UNDER MHD 06 PUBLISHED BEFORE YEAR 2000

S. No	IS No.	Title	Status
1.	IS 6779 : 1989	Thoracic Surgery Instruments - Forceps Dissecting and Ligature Mixer s Pattern	To be decided
2.	IS 7971 : 1987	Tourniquet Cardiovascular Rumel-Belmont s Pattern	To be decided
3.	IS 7345 : 1994	Cardiovascular Surgery Instruments - Anastomosis Forceps and Clamps - Patterns Shapes and Dimensions	Reaffirmed
4.	IS 8317 : 1991	Cardiovascular Surgery Instruments - Clamps Vascular Angled at 45 - Shape and Dimensions	Reaffirmed
5.	IS 8335 : 1991	Cardiovascular Surgery Instruments - Clamps Auricle Satinsky Pattern - Sizes Shape and Dimensions	Reaffirmed
6.	IS 8890 : 1991	Thoracic Surgery Instruments - Clamps Bronchus - Types Shapes and Dimensions	Reaffirmed
7.	IS 10540 : 1991	Cardiovascular Surgery Instruments - Clamps Atrial Appendage Glover s Pattern - Shape and Dimensions	Reaffirmed
8.	IS 10541 : 1991	Cardiovascular Surgery Instruments - Clamps Vena Cava Satinsky Pattern - Shape Sizes and Dimensions	Reaffirmed
9.	IS 13940 : 1994	Cardiovascular Surgery Instruments - Clamps Bulldog DeBakey Ring Handle - Shape and Dimensions	Reaffirmed
10.	IS 9928 : 1981	Clamp Aortic DeBakey s Pattern Spoon Shaped angled Jaw	WC (20931)
11.	IS 9950 : 1981	Clamp Vascular Wister Pattern	WC (20932)
12.	IS 9951 : 1981	Scissors Blunt End Nelson Pattern	WC (20933)
13.	IS 9987 : 1981	Clamps Multipurpose De-bakey s Pattern	WC (20934)
14.	IS 6395 : 1989	Thoracic Surgery Instruments - Clamps Auricle Crafoord s Pattern	WC (20912)
15.	IS 6436 : 1989	Thoracic Surgery Instruments - Rib Spreader Finochietto s Pattern Adult Size	WC (20913)
16.	IS 6442 : 1989	Thoracic Surgery Instruments - Shears Rib Tudor Edward s Pattern for Posterior End of Ribs	WC (20914)
17.	IS 7346 : 1987	Raspatories Rib Semb s Pattern	WC (20911)
18.	IS 7355 : 1987	Spreader Rib Tuffier s Pattern Adult Size	WC (20922)
19.	IS 7367 : 1987	Clamps Coarctation Potts Pattern Straight and Angular	WC (20923)
20.	IS 7379 : 1987	Clamps Patent Ductus Potts Pattern Straight and Angular	WC (20924)
21.	IS 7382 : 1987	Shears Rib Price Thomas Pattern	WC (20925)
22.	IS 7972 : 1987	Scissors Dissecting Metzenbaum s Pattern	WC (20928)

23.	IS 11566 :1986	Valve Retractors	WC (20935)
24.	IS 6466 : 1989	Thoracic and Cardiovascular Surgery Instruments - Needle Holders	WC (20915)
25.	IS 6467 : 1989	Thoracic Surgery Instruments - Periosteotome Rib Alexander s Pattern	WC (20916)
26.	IS 6468 : 1989	Thoracic Surgery Instruments - Trocar Empyema Nelson s Pattern	WC (20917)
27.	IS 6777 : 1989	Thoracic and Cardiovascular Surgery Instruments - Forceps Dissecting Lung	WC (20919)
28.	IS 6778 : 1989	Thoracic Surgery Instruments - Forceps Lung Duval s Pattern	WC (20920)
29.	IS 6780 : 1989	Thoracic Surgery Instruments - Forceps Artery Robert s Pattern Curved on Flat	WC (20921)
30.	IS 7399 : 1987	Knife Sternum Lebsche s Pattern	WC (20926)
31.	IS 7434 : 1987	Retractor Scapula Tudor Edward s Pattern	WC (20927)
32.	IS 8345 : 1994	Cardiovascular surgery instruments - Clamps bulldog cross action type	WC (20929)
33.	IS 8549 : 1991	Cardiovascular Surgery Instruments - Angled Scissors Potts Smith Pattern	WC (20930)