BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06)	17	Thursday, 23 Apr 2024 **04:00 PM**
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=mbaed217d1c3a9b0d5725f7d25f8ede8f **Meeting Number**: 2514 012 2172 **Password**: MHD06@17 (64306117 from video systems)		
Chairperson Dr. Deepak Kumar Satsangi (In personal Capacity)	**Member Secretary** Mr. Pawan Kumar Scientist B/Assistant Director, MHD, BIS	

ITEM 0 GENERAL

0.1 WELCOME ADDRESSES BY MEMBER SECRETARY

0.2 OPENING REMARKS BY HEAD, MHD

0.3 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the previous meeting of Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06) held on 22 Feb 2024 approved by the Chairperson was circulated to all members through the BIS portal vide letter no: MHD 06 dated 1 Apr 2024.

1.2 No comments have been received so far.

The Committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06) is as follows:

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)

The Committee may please note and review the scope.

2.2 The present composition of Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06) along with participation status of members is enclosed at ***Annexure 1***.

2.3. Functional categories wise analysis:

Category	Current	Balanced	Co-option in hand	Vacancy	Percent current	Percent after
Academic Institution	5	9	0	4	28%	30%
Central Ministry/Dept.	1	1	0	0	6%	3%
Consumer Group	1	1	0	0	6%	3%
Industry	6	10	5	4	33%	33%
R&D Organization	2	6	0	4	11%	20%
Regulatory Body	1	1	0	0	6%	3%
Expert	2	2	0	0	11%	7%
Total	**18**	**30**		**12**		

2.4 Requests have been received from the following for representation on the Committee:

Sl. No.	Organisation	Nomination
1.	AiMED	Mr. Mohit Bajaj, Mr. Saurabh Patel, Mr. C.S. Prasad
2.	MTAi	Ms. Preety Sharma, Edwards Lifesceinces India Mr. Sandeep Verma, India Medtronic Pvt. Ltd. Ms. Latika Vats, India Medtronic Pvt. Ltd. Mr. Anand Gupta, India Medtronic Pvt. Ltd. Mr. Kshitij Agarwal, India Medtronic Pvt. Ltd.
3.	FICCI	Mr. Abhijeet Singhvi, Vice President - R&D, Sahajanand Medical Technologies Ltd.
4	India Medtronic Pvt. Ltd.	Anand Gupta, Kshitij Agarwal
5	Edwards Lifesciences Pvt. Ltd.	Ms Preety Sharma, Head, Regulatory Affairs

The committee may decide.

2.5 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned considering that non-industry representation should not be less than two-third of the committee composition, as far as possible.

The committee may please note and review the composition.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The following draft Indian Standards / Amendments have been sent for wide circulation:

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1	MHD/06/24992	Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2	*Last date over*	*No comments received*
2	MHD/06/24999	Cardiovascular implants and artificial organs Cannulae for extracorporeal circulation	*Last date over*	*No comments received*
3	MHD/06/25000	Cardiovascular implants Transcatheter cardiac occluders	*Last date over*	*No comments received*
4	MHD/06/25002	Implants for surgery Active implantable medical devices Part 4: Implantable infusion pump systems	*Last date over*	*No comments received*

3.2 No comments have been received and the above documents may be taken up for finalization.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The following draft Indian Standards / Amendments are ready for wide circulation:

Sl. No.	Document No./ Standard No.	Title
1.	IS 7345	Cardiovascular surgery instruments – Anastomosis forceps and clamps – Pattern, shapes and dimensions (Third Revision)
2.	IS 8317	Cardiovascular surgery instruments – Clamps, vascular, angled at 45 – Shape and dimensions (Second Revision)
3.	IS 8335	Cardiovascular surgery instruments – Clamps, Auricle, Satinsky Pattern – Sizes, Shape and Dimensions (First Revision)
4.	IS 8890	Thoracic surgery instruments – Clamps, bronchus – Types, shapes and dimensions (Second revision)
5.	IS 10540	Cardiovascular surgery instruments – Clamps, Atrial Appendage, Glover's Pattern – Shape and Dimensions (First revision)
6.	IS 10541	Cardiovascular surgery instruments – Clamps vena cava, satinsky pattern shape, sizes and dimensions (Second revision)
7.	IS 13940	Cardiovascular surgery instruments – Clamps, bulldog, DeBakey, ring handle – Shape and dimensions (First revision)
8	IS 6436	Thoracic Surgery Instruments - Rib Spreader, Finochietto's Pattern, Adult Size
9	IS 6777	Thoracic and cardiovascular surgery instruments - Forceps, dissecting, lung - Specification (First Revision)
10	IS 7367	Clamps, Coarctation, Potts' Pattern, Straight and Angular
11	IS 7399	Knife, Sternum, Lebsche's Pattern
12	IS 8345	Cardiovascular surgery instruments - Clamps, bulldog, cross action type - Specification (First Revision)
13	IS 9928	Clamp, Aortic, DeBakey's Pattern (Spoon Shaped angled Jaw)

The Committee may kindly approve.

ITEM 5 DRAFT UNDER PREPARATION

- The list of subjects for which a working draft is under preparation is attached at *Annexure 2*

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

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

7.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also define thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental and economic consideration.

The Committee may kindly note.

ITEM 8 TECHNICAL ISSUES

8.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 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' (P Member)

The information regarding the working groups along with the participation status is as follows:

Committee		Current Members
ISO/TC 150/SC 2		
ISO/TC 150/SC 2/WG 1	Cardiac valves	Ms. Gayathri Nair, Meril Life Sciences Private Limited Mr. Pawan Kumar, Sc-B, BIS
ISO/TC 150/SC 2/WG 3	Vascular prostheses	-- *No representation* --
ISO/TC 150/SC 2/WG 4	Blood gas exchangers	-- *No representation* --
ISO/TC 150/SC 2/WG 5	Renal replacement, detoxification and apheresis	-- *No representation* --
ISO/TC 150/SC 2/WG 6	Vascular device-drug combination products	Shri Narendra Patel, Meril Life Sciences Private Limited Mr. Pawan Kumar, Mr. Pawan Kumar, Sc-B, BIS
ISO/TC 150/SC 2/WG 7	Cardiovascular absorbable implants	-- *No representation* --
ISO/TC 150/SC 6		
ISO/TC 150/SC 6/JWG 1	Joint ISO/TC 150/SC 6 - IEC/SC 62D WG: Cardiac pacemakers and implantable defibrillators	Pawan Kumar, Sc-B, BIS
ISO/TC 150/SC 6/JWG 2	JWG between ISO/TC 150/SC 6 and IEC/SC62B: Effects of magnetic resonance imaging on active implantable medical devices	Pawan Kumar, Sc-B, BIS
ISO/TC 150/SC 6/WG 1	Fundamental standards	Pawan Kumar, Sc-B, BIS

9.2 ISO/TC 150 Implants for surgery has announced the meeting (Face-to-Face) along with all its subcommittees and working groups from 09 Sep 2024 to 13 Sep 2024 in Berlin, Germany. In this regard, nominations are invited from members to be a part of the Indian delegation for ISO/TC 150/SC 2 and ISO/TC 150/SC 6. The interested members may submit their nominations on or before 23 April 2024, so that delegation proposals can be processed for the meeting.

9.3 The ISO Standards published under ISO/TC/150/SC2 and ISO/TC 150/SC6 along with their status of adoption is given in ***Annexure 3***.

9.4 Given that BIS holds a Participating membership in these technical committees, it is crucial for its members to vote on the notified ballots. An updated list of ballots received since the previous meeting, along with the votes cast by us as the national mirror committee, can be found in ***Annexure 4***.

ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

10.2 Review of Indian Standards (pre-2000 Standards)

10.2.1 All the Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archived in the light of technological developments that have happened so far in relation to these standards.

10.2.2 The list of such Indian Standards is given at ***Annexure 5***.

The Committee may kindly review.

10.3 Review of Indian Standards (as per 5-year cycle)

10.3.1 As per the policy of BIS, the Indian Standards which have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

10.3.2 With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document in respect of each of the Indian Standards which are due for revision.

The Committee may kindly note.

ITEM 11 DATE AND PLACE OF NEXT MEETING

11.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 06 is scheduled on **Tuesday, July 23, 2024**.

The Committee may kindly note.

ITEM 13 ANY OTHER BUSINESS

Annexure 1
MHD 06 Composition along with participation status in last 3 meetings

S.no	Organization	Attendance
1	Dr. Deepak Kumar Satsangi, In Personal Capacity	3
2	All India Institute of Medical Sciences, New Delhi	1
3	Boston Scientific India Private Limited, Gurugram	2
4	Central Drugs Standard Control Organization, New Delhi	2
5	Indian Heart Foundation, Hyderabad	1
6	Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry	2
7	Johnson and Johnson Private Limited, Mumbai	3
8	Kalam Institute of Health Technology, Vishakhapatnam	2
9	Meril Life Sciences Private Limited, Vapi	2
10	Ministry of Electronics and Information Technology, New Delhi	2
11	North-Eastern Hill University, Shillong	2
12	Post Graduate Institute of Medical Education and Research, Chandigarh	2
13	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	2
14	TTK Healthcare Limited (Heart Valve), Chennai	2
15	Abbott Healthcare India Private Limited, Mumbai	New
16	Integral Institute of Medical Science And Research, Lucknow	New
17	Stryker India Private Limited, Gurugram	New
18	Teleflex Medical Private Limited, Bengaluru	New

Annexure 2
Drafts under preparation

Sr. No.	Subject of standardization
1.	Electrocardiograph electrode
2.	Battery operated sternum saw system
3.	Rotablation Machine
4.	Arterial Line Filter
5.	Heart Lung Pack
6.	Cardioplegia Delivery System
7.	Mister Blower
8.	Cardioplegia Perfusion Adaptors
9.	Cardiotomy Reservoir
10.	Pre Bypass Filter
11.	Cardioplegia Filters
12.	Rigid Sucker
13.	Coronary Perfusion Cannulae
14.	Vessel Cannulae
15.	Aortic Root Cannulae
16.	Lv Vents
17.	Inter Coastal Drainage System
18.	Aortic Perfusion Cannulae
19.	Venous Cannula
20.	Femoral Venous Cannula
21.	Femoral Aortic Cannula
22.	Arteriotomy Cannulae
23.	Cardiac Sump
24.	Flexible Suction Catheter
25.	Vaccum Relief Check Valve
26.	Intravascular Shunt
27.	Dynamic Bubble Trap
28.	Double Lumen Left Heart Catheter
29.	Isolators
30.	Level Sensor Pad
31.	Haemoconcentrator
32.	Vascular Loop
33.	Aortic Punch
34.	Under Water Seal Drainage Bottle
35.	Suture Holder
36.	Manifold Kit

Annexure 3
ISO Standards published under ISO/TC/150/SC2 and ISO/TC 150/SC6 along with their status of adoption

Sr. No.	Standard no	Title	Status of adoption
1	ISO/PAS 7020:2023	Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2	Under adoption
2	ISO 18193:2021	Cardiovascular implants and artificial organs — Cannulae for extracorporeal circulation	Under adoption
3	ISO 22679:2021	Cardiovascular implants — Transcatheter cardiac occluders	Under adoption
4	ISO 7199:2016/Amd 1:2020	Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators) — Amendment 1: Connectors	Adopted
5	ISO/TR 12417-2:2022	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 2: Local regulatory information	Adopted
6	ISO 15674:2016/Amd 1:2020	Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags — Amendment 1: Connectors	Adopted
7	ISO 15675:2016/Amd 1:2020	Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters — Amendment 1: Connectors	Adopted
8	ISO 18241:2016/Amd 1:2019	Cardiovascular implants and extracorporeal systems — Cardiopulmonary bypass systems — Venous bubble traps — Amendment 1: Connectors	Adopted
9	ISO 18242:2016/Amd 1:2023	Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps — Amendment 1: Worst-case conditions for testing	Adopted
10	ISO/TS 23810:2018	Cardiovascular implants and artificial organs — Checklists for use of extracorporeal circulation equipment	Adopted
11	ISO 5840-1:2021	Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements	Adopted
12	ISO 5840-2:2021	Cardiovascular implants — Cardiac valve prostheses — Part 2: Surgically implanted heart valve substitutes	Adopted
13	ISO 5840-3:2021	Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques	Adopted
14	ISO 5910:2018	Cardiovascular implants and extracorporeal systems — Cardiac valve repair devices	Adopted
15	ISO 7198:2016	Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches	Adopted
16	ISO 7199:2016	Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)	Adopted
17	ISO 8637-1:2017	Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators	Adopted

18	ISO 8637-2:2018	Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters	**Adopted**
19	ISO 8637-3:2018	Extracorporeal systems for blood purification — Part 3: Plasmafilters	**Adopted**
20	ISO 11658:2012	Cardiovascular implants and extracorporeal systems — Blood/tissue contact surface modifications for extracorporeal perfusion systems	**Adopted**
21	ISO 12417-1:2015	Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements	**Adopted**
22	ISO 15674:2016	Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags	**Adopted**
23	ISO 15675:2016	Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line filters	**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/TS 17137:2021	Cardiovascular implants and extracorporeal systems — Cardiovascular absorbable implants	**Adopted**
26	ISO 18241:2016	Cardiovascular implants and extracorporeal systems — Cardiopulmonary bypass systems — Venous bubble traps	**Adopted**
27	ISO 18242:2016	Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps	**Adopted**
28	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	**Adopted**
29	ISO 23500-1:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements	**Adopted**
30	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	**Adopted**
31	ISO 23500-3:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies	**Adopted**
32	ISO 23500-4:2019	Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies	**Adopted**
33	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	**Adopted**
34	ISO 25539-1:2017	Cardiovascular implants — Endovascular devices — Part 1: Endovascular prostheses	**Adopted**
35	ISO 25539-2:2020	Cardiovascular implants — Endovascular devices — Part 2: Vascular stents	**Adopted**
36	ISO 25539-3:2011	Cardiovascular implants — Endovascular devices — Part 3: Vena cava filters	**Adopted**
37	ISO 25539-4:2021	Cardiovascular implants — Endovascular devices — Part 4: Application of ISO 17327-1 for coated endovascular devices	**Adopted**
38	ISO 5841-2:2014	Implants for surgery — Cardiac pacemakers — Part 2: Reporting of clinical performance of populations of pulse generators or leads	**Adopted**

39	ISO 5841-3:2013	Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers	**Adopted**
40	ISO/TS 10974:2018	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device	**Under adoption**
41	ISO 11318:2002	Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements	**Adopted**
42	ISO 14117:2019	Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices	**Adopted**
43	ISO 14708-1:2014	Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer	Adopted by other committee
44	ISO 14708-2:2019	Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers	Adopted by other committee
45	ISO 14708-3:2017	Implants for surgery — Active implantable medical devices — Part 3: Implantable neurostimulators	Adopted by other committee
46	ISO 14708-4:2022	Implants for surgery — Active implantable medical devices — Part 4: Implantable infusion pump systems	**Under adoption**
47	ISO 14708-5:2020	Implants for surgery — Active implantable medical devices — Part 5: Circulatory support devices	**Adopted**
48	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)	**Adopted**
49	ISO 14708-7:2019	Implants for surgery — Active implantable medical devices — Part 7: Particular requirements for cochlear and auditory brainstem implant systems	Adopted by other committee
50	ISO/TR 21900:2018	Guidance for uncertainty analysis regarding the application of ISO/TS 10974	**Under adoption**
51	ISO 27185:2012	Cardiac rhythm management devices — Symbols to be used with cardiac rhythm management device labels, and information to be supplied — General requirements	**Adopted**
52	ISO 27186:2020	Active implantable medical devices — Four-pole connector system for implantable cardiac rhythm management devices — Dimensional and test requirements	**Adopted**
53	IEC 60601-2-31:2020	Medical electrical equipment — Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	**Under adoption**

Annexure 4
List of ballots received since the previous meeting along with the status of vote casted

Sr. No.	TC	Reference no.	Ballot type	Title	Opening date	Closing date	Voting status
1	SC 6	ISO 5841-3:2013 (Ed 3, vers 2)	Systematic review	Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers	15 October 2023	03 March 2024	Approved
2	SC 6	ISO 11318:2002 (Ed 2, vers 4)	Systematic review	Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements	15 October 2023	03 March 2024	Approved
3	SC 2	ISO/FDIS 23500-3 (Ed 2)	FDIS	Water for haemodialysis and related therapies	19 January 2024	15 March 2024	Abstain
4	SC 2	ISO/FDIS 23500-4 (Ed 2)	FDIS	Concentrates for haemodialysis and related therapies	19 January 2024	15 March 2024	Abstain
5	SC 2	ISO/FDIS 23500-5 (Ed 2)	FDIS	Quality of dialysis fluid for haemodialysis and related therapies	19 January 2024	15 March 2024	Abstain
6	SC 2	ISO/CD TR 18965	CD	CD (Committee Draft Consultation)	27 January 2024	23 March 2024	No comments
7	SC 2	ISO 5840-1:2021/DAmd 1 (Ed 2)	AMD	ISO 5840-1:2021/DAmd 1 (Ed 2)	07 February 2024	01 May 2024	Approved
8	SC 2	ISO 5840-2:2021/DAmd 1 (Ed 2)	AMD	ISO 5840-2:2021/DAmd 1 (Ed 2)	07 February 2024	01 May 2024	Approved
9	SC 2	ISO 5840-3:2021/DAmd 1 (Ed 2)	AMD	ISO 5840-3:2021/DAmd 1 (Ed 2)	06 February 2024	30 April 2024	Approved
10	SC 2	ISO/FDIS 23500-1 (Ed 2)	FDIS	Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements	20 February 2024	16 April 2024	Approved
11	SC 2	ISO/FDIS 8637-3 (Ed 2)	FDIS	Extracorporeal systems for blood purification — Part 3: Plasmafilters	23 February 2024	19 April 2024	Approved
12	SC 2	ISO/FDIS 8637-1 (Ed 2)	FDIS	Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters,	23 February 2024	19 April 2024	Approved

				haemofilters and haemoconcentrators			
13	SC 2	ISO/FDIS 23500-2 (Ed 2)	FDIS	Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies	26 February 2024	22 April 2024	**Approved**
14	SC 2	Draft Resolution ISO/TC 150/SC2 2024/01 by correspondence	CIB (Committee Internal Ballot)	Resolution to initiate the revision of ISO 7198:2016, Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches	13 March 2024	12 April 2024	**Approved**

Annexure 5
Pre-2000 Standards

Sl. No.	Standard No.	Title
1.	IS 7345 : 1994	Cardiovascular surgery instruments – Anastomosis forceps and clamps – Pattern, shapes and dimensions (Third Revision)
2.	IS 8317 : 1991	Cardiovascular surgery instruments – Clamps, vascular, angled at 45 – Shape and dimensions (Second Revision)
3.	IS 8335 : 1991	Cardiovascular surgery instruments – Clamps, Auricle, Satinsky Pattern – Sizes, Shape and Dimensions (First Revision)
4.	IS 8890 : 1991	Thoracic surgery instruments – Clamps, bronchus – Types, shapes and dimensions (Second revision)
5.	IS 10540 : 1991	Cardiovascular surgery instruments – Clamps, Atrial Appendage, Glover's Pattern – Shape and Dimensions (First revision)
6.	IS 10541 : 1991	Cardiovascular surgery instruments – Clamps vena cava, satinsky pattern shape, sizes and dimensions (Second revision)
7.	IS 13940 : 1994	Cardiovascular surgery instruments – Clamps, bulldog, DeBakey, ring handle – Shape and dimensions (First revision)
8	IS 6436 : 1989	Thoracic Surgery Instruments - Rib Spreader, Finochietto's Pattern, Adult Size
9	IS 6777 : 1989	Thoracic and cardiovascular surgery instruments - Forceps, dissecting, lung - Specification (First Revision)
10	IS 7367 : 1987	Clamps, Coarctation, Potts' Pattern, Straight and Angular
11	IS 7399 : 1987	Knife, Sternum, Lebsche's Pattern
12	IS 8345 : 1994	Cardiovascular surgery instruments - Clamps, bulldog, cross action type - Specification (First Revision)
13	IS 9928 : 1981	Clamp, Aortic, DeBakey's Pattern (Spoon Shaped angled Jaw)