



## भारतीय मानक ब्यूरो BUREAU OF INDIAN STANDARDS

### 17<sup>th</sup> Meeting of Medical and Surgical Cardiology Equipment Sectional Committee, MHD 06

#### Minutes

दिनांक तथा दिन DATE & DAY	23 Apr 2024, Thursday
समय TIME	04:00 PM
स्थान VENUE	Hybrid Meeting
चेयरमैन CHAIRMAN	<b>Dr. Deepak Kumar Satsangi</b> (In personal Capacity)
सदस्य सचिव MEMBER SECRETARY	<b>Mr. Pawan Kumar</b> Scientist-B and Assistant Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards

#### ITEM 0 GENERAL

- 0.1 Mr. Pawan Kumar, Scientist B, MHD, BIS welcomed the members to 17<sup>th</sup> meeting of Medical and Surgical Cardiology Equipment Sectional Committee MHD 06. He appreciated the members present for sparing their valuable time to participate in this meeting.
- 0.2 Shri A R Unnikrishnan, Head (MHD), BIS in his opening remarks summarized the work done by the committee in the last financial year, mentioning 2 published standards, 19 standards are under publication and 23 standards are under development. He further informed about the statues of adopted standards under harmonized standards that, out of 53, 46 standards have already been adopted and rest 7 are under process to be adopted. He mentioned the significant increase in meeting attendance (21.88 to 92.86) and efficiency index (11.67 to 49.11) instantiated by reforms introduced by BIS in the preceding year. He discussed various parameters i.e. no. of standards published, commenting on drafts,



meeting attendance and no. of wide circulation draft etc. based on which efficiency index for technical committees is calculated. He also discussed his meeting with the Secretary, DoP, MoC&F regarding standard development in the healthcare sector. He urged the members to increase the work in hand by identifying more subjects for standard development relevant to the current committee.

Additionally, Shri A R Unnikrishnan, Head (MHD) informed the committee that he would be having a separate meeting with the experts nominated in each working group of ISO TC and SC. He reiterated that the members nominated in technical committees and working groups of ISO should actively contribute. He concluded his remarks by urging the committee members for active and fruitful deliberations.

- 0.3 Dr. Deepak Kumar Satsangi, the Chairperson, extended a warm welcome to the attendees of the 17<sup>th</sup> meeting of the Medical Laboratory Instruments Sectional Committee MHD 06. He urged committee members for active deliberations to make the meeting successful. He requested the Member Secretary to take up the agenda items for discussion. He requested the Member Secretary to take up the agenda items for discussion.

*The list of participants is given in ANNEX A.*

## **ITEM 1 CONFIRMATION TO THE MINUTES OF THE LAST MEETING**

The Committee formally confirmed the minutes of the last meeting of the Medical and Surgical Cardiology Sectional Committee (MHD 06), held on 22nd Feb 2024 via Video Conferencing (Webex).

## **ITEM 2 SCOPE AND COMPOSITION OF THE SECTIONAL COMMITTEE**

- 2.1** The committee noted the current scope of the Medical and Surgical Cardiology Sectional Committee MHD 06.
- 2.2** The Committee noted the current composition of the Medical and Surgical Cardiology Sectional Committee (MHD 06) attached at ANNEX A of agenda.
- 2.3** The committee noted information provided at agenda item 2.3.
- 2.4** The committee had a comprehensive deliberation regarding the request for representation in the existing committee. Following is the status of committee:



Sl. No.	Organization	Nomination	Status
1.	AiMED	Mr. Mohit Bajaj, Mr. Saurabh Patel, Mr. C.S. Prasad	Membership accepted
2.	MTAi	Ms. Preety Sharma, Edwards Lifesciences 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.	Membership accepted
3.	FICCI	Mr. Abhijeet Singhvi, Vice President - R&D, Sahajanand Medical Technologies Ltd.	Membership accepted
4	India Medtronic Pvt. Ltd.	Anand Gupta, Kshitij Agarwal	Membership was not accepted as the organization is already represented through the Industry Association (MTAi).
5	Edwards Lifesciences Pvt. Ltd.	Ms Preety Sharma, Head, Regulatory Affairs	Membership was not accepted as the organization is already represented through the Industry Association (MTAi).

2.5 The committee noted information provided at agenda item 2.5

### ITEM 3 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION

Since no comments were received on the document listed in the table below during the wide-circulation period, the committee decided to finalize the document in the current form and recommended for further processing to publish as Indian Standard.

Sl. No.	Document No.	Title	Committee recommendation
1.	MHD/06/24992	Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2	<i>Finalized</i>
2	MHD/06/24999	Cardiovascular implants and artificial organs Cannulae for extracorporeal circulation	<i>Finalized</i>
3	MHD/06/25000	Cardiovascular implants Transcatheter cardiac occluders	<i>Finalized</i>
4	MHD/06/25002	Implants for surgery Active implantable medical devices Part 4: Implantable infusion pump systems	<i>Finalized</i>



## **ITEM 4 DRAFT STANDARD/ AMENDMENT FOR APPROVAL FOR APPROVAL FOR WIDE CIRCULATION**

The committee thoroughly deliberated upon the subject listed in Item 4.1 of the agenda and decided to wide circulate the following standards for a period of 90 days.

<b>Sl. No.</b>	<b>Document No./ Standard No.</b>	<b>Title</b>
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)

## **ITEM 5 DRAFT UNDER PREPARATION**

The committee noted information provided at agenda item 5.

## **ITEM 6 COMMENTS ON PUBLISHED STANDARDS**

The committee acknowledged the information presented in agenda item 6.

## **ITEM 7 NEW SUBJECTS**

The committee acknowledged the information presented in agenda item 7.



## ITEM 8 TECHNICAL ISSUES

The committee noted information provided at agenda item 8.

## ITEM 9 INTERNATIONAL ACTIVITIES

9.1 The committee noted the information provided at the agenda item 9.1. As per the direction received from Head (MHD), all the experts representing India in the ISO working group has to brief the committee about the activities going on in the nominated working group.

In this regard, Ms. Gayathri Nair representing Meril Life Sciences Private Limited, Vapi explained about the activities going on in ISO/TC 150/SC 2/WG 1 “Heart Valves”. She informed the committee that bioprosthetic heart valves are currently the state-of-the-art treatment for the stenosed valves. She informed the committee that there are three major activities going on in the aforementioned working group:

1. The entire regulatory approach is going in the risk-based approach and a separate technical report is being prepared and finalized on the manufacturing of cardiac valves. The document is going to be published very soon and the same will be very helpful in risk management associated with bioprosthetic heart valves manufacturing.
2. Few complaints have been received on surgical bio prosthetic valves durability issues. Even after testing the valves according to ISO 5840 and approved by regulatory authorities, the valve fails following implant. To investigate this, a subgroup is formed to address the durability issues and investigation is going on whether the standard is adequate to minimize risk associated with durability of bioprosthetic valves.
3. A round-robin study on the valve performance assessed by Pulsatile Flow Testing is being conducted and results of different laboratories are being compared. It was found that the results of different laboratories were varying. The variation in test results is being taken care of in the updated ISO standard. Similar studies are being planned by a task force for other similar parameters i.e. leakage of valves etc.

The committee appreciated Ms. Gayathri Nair for briefing the committee regarding the activities of ISO working group on Cardiac Valves. Her participation and contributions will ensure that no decision is made without consideration of Indian point of view.

Furthermore, Shri Pawan Kumar, MS, MHD 06 mentioned that there are many working groups of ISO TC for which MHD 06 is National Mirror Committee (NMC) but despite of having diverse pool of experts in the committee, we do not have Indian representation. In this regard, members were invited to send their nominations for representation in the ISO working group.

9.2 The committee noted the information provided on agenda item 9.2 and suggested the BIS Secretariat to attend the Working group meetings along with the Plenary Meetings to understand the current work going on in ISO/TC 150/SC 2 and ISO/TC 150/SC 6. In this regard, Shri Pawan Kumar, Sc-B, is approved to be part of the Indian delegation and to attend the following meetings of ISO/TC 150/SC 6 :



Committee	Dates	Mon. 2024-09-09	Tue. 2024-09-10	Wed. 2024-09-11	Thu. 2024-09-12	Fri. 2024-09-13
ISO/TC 150/SC 6	2024 September 12				15:30-18:00 +02:00 Europe/Berlin	
ISO/TC 150/SC 6/JWG 1	2024 September 9-11	14:00-18:00 +02:00 Europe/Berlin	08:00-18:00 +02:00 Europe/Berlin	08:00-18:00 +02:00 Europe/Berlin		
ISO/TC 150/SC 6/WG 1	2024 September 12-13				08:00-12:30 +02:00 Europe/Berlin	08:00-12:30 +02:00 Europe/Berlin

It may also be noted that he is already registered as expert in ISO/TC 150/SC 6/JWG 1 “Cardiac Pacemaker and Implantable Defibrillators” and ISO/TC 150/SC 6/WG 1 “Fundamental Standards”.

9.3 The committee acknowledged the information presented in agenda item 9.3 on adoption status of ISO standards relevant to the committee.

9.4 The committee acknowledged the information presented in agenda item 9.4 on voting status of ISO ballots.

## ITEM 10 PROGRAMME OF WORK

10.1 The Committee noted the present program of work of Medical and Surgical Cardiology Equipment Sectional Committee (MHD 06).

10.2 The committee noted the list of pre-2000 Standards provided at Annexure 5 of agenda.

10.3 The committee noted information provided at agenda item 10.3

## ITEM 11 DATE AND PLACE OF NEXT MEETING

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

MHD06	Q1, 2024-25	Q2, 2024-25	Q3, 2024-25	Q4, 2024-25
	April	July	November	February
	Tuesday, April 23, 2024	Tuesday, July 23, 2024	Tuesday, November 19, 2024	Tuesday, February 18, 2025



## **ITEM 12 ANY OTHER BUSINESS**

There being no other business, the meeting ended with a vote of thanks to the hon'ble chair and all the members present.

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## ANNEX A

### List of participants

S.No.	Organization	Member	Mode
1	In Personal Capacity	Dr. Deepak Kumar Satsangi	Physical
2	Abbott Healthcare India Private Limited, Mumbai	Ms. Lipi Chakhaiyar	Physical
		Ms. Shweta Sharma	Physical
3	All India Institute of Medical Sciences, New Delhi	Dr. Milind P Hote	Virtual
4	Boston Scientific India Private Limited, Gurugram	Shri Prashanth Prabhakar	Virtual
		Shri Dev Chopra	Virtual
5	Central Drugs Standard Control Organization, New Delhi	Shri Ajai Basil	Virtual
		Shri Umang Varshney	Virtual
6	Indian Heart Foundation, Hyderabad	Dr Sevith Rao	Virtual
7	Integral Institute of Medical Science And Research, Lucknow	Pro Dr Abha Chandra	Virtual
8	Jawahar Lal Institute of Post Graduate Medical Education and Research, Puducherry	Dr. Ramsankar P	Virtual
9	Johnson and Johnson Private Limited, Mumbai	Ms. Aishwarya Chandran	Virtual
10	Kalam Institute of Health Technology, Vishakhapatnam	Shri Santosh Kumar Balivada	Virtual
11	Meril Life Sciences Private Limited, Vapi	Ms. Gayathri Nair	Virtual
12	Ministry of Electronics and Information Technology, New Delhi	Shri Rashid Shabhan	Virtual
13	North-Eastern Hill University, Shillong	Dr. Sudip Paul	Virtual
		Dr. Shyamal Mandal	Virtual
14	Post Graduate Institute of Medical Education and Research, Chandigarh	Prof Bikash medhi	Virtual
15	Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram	Shri D S Nagesh	Virtual
		Shri. Vinodkumar V	Virtual
		Ms. Amrutha C	Virtual
16	Stryker India Private Limited, Gurugram	Shri Deepak Sharma	Virtual
17	TTK Healthcare Limited (Heart Valve), Chennai	Ms. Indu V Nair	Virtual
		Dr. Anupama V Raj	Virtual
18	Teleflex Medical Private Limited, Bengaluru	Shri Ankur Datta	Virtual
19	In Personal Capacity	Shri Asok Kumar Raghavan Nair	Virtual