



**भारतीय मानक ब्यूरो**  
**BUREAU OF INDIAN STANDARDS**

**चिकित्सा प्रयोगशाला उपकरण अनुभागीय समिति एम.एच.डी 10 की सोलहवीं बैठक**  
**Sixteenth Meeting of Medical Laboratory Instruments Sectional Committee, MHD10**

**कार्यव्रत | Minutes**

<b>दिनांक तथा दिन   Date &amp; Day</b>	<b>27 January 2023, Friday</b>
<b>समय   Time</b>	<b>11:00 AM</b>
<b>स्थान   Venue</b>	<b>Virtual Meeting (WebEx)</b>
<b>चेयरमैन   Chairman</b>	<b>Dr. Achin K. Sen</b> Associate Professor - Pathology North Delhi Municipal Corporation Medical College & Hindu Rao Hospitals, Delhi

**ATTENDEES:**

<b>Sl No.</b>	<b>Organization</b>	<b>Name</b>
1)	NDMC Medical College and Hindu Rao Hospital, New Delhi	Dr. A. K. Sen ( <i>Chairman</i> )
2)	All India Institute of Medical Sciences, New Delhi	Dr. Sudip Datta
		Dr. Tushar Sehgal
3)	Association of Indian Medical Device Industry, New Delhi	Shri Rakesh Jain
4)	Bharati Vidyapeeth Medical College, Pune	Col Mahadevan Kumar
5)	Borosil Glass Works Limited, Mumbai	Shri Satish Chitriv
6)	CSIR - National Physical Laboratory, New Delhi	Dr. Tuhin Kumar Mandal
7)	CSIR-Central Scientific Instruments Organisation, Chandigarh	Dr. Neelesh Kumar
8)	Directorate General of Health Services, New Delhi	Dr. Naresh Panchal
9)	Dr D. Y. Patil Medical College, Hospital and Research Centre, Pune	Dr. Chandrashekhar G. Raut
10)	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri P. K. Sharma
11)	Kalam Institute of Health Technology,	Ms. Sushmita Roy



Minutes for the Sixteenth meeting of the Medical Laboratory Instruments  
Sectional Committee, MHD-10  
(For BIS use only)



<i>Sl No.</i>	<i>Organization</i>	<i>Name</i>
	Vishakhapatnam	Ms. Priyadarshini A
12)	National Accreditation Board for Testing and Calibration Laboratories, Gurugram	Ms. Gayathri S.
13)	Schott Glass India Private Limited, Pune	Ms. Sugna Verma
14)	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.
15)	Thermo Fisher Scientific India Private Limited, Mumbai	Shri Vijay Kumar
16)	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Rajni Dawar
17)	Voluntary Organisation in Interest of Consumer Education (VOICE), New Delhi	Shri M. A. U. Khan

**BIS DIRECTORATE GENERAL:**

1)	Vinit Vidyadhar Bansod ( <i>Member Secretary</i> )	Scientist B/Assistant Director, MHD, BIS
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**ITEM 0 WELCOME AND OPENING REMARKS**

**ITEM 0.1** Member Secretary presented his greetings to all the members present in the meeting. Meeting commenced with the introduction of the members.

**ITEM 0.2 Opening remarks by Chairperson**

Dr. A. K. Sen, Chairman MHD-10, welcomed all the members to the 16<sup>th</sup> meeting of the Medical Laboratory Instruments Sectional Committee (MHD-10) and apprised the committee about the agenda of the meeting, which is decision on request of transfer of subjects from MHD-12 to MHD-10 and discussion on developments in the revision of standards.

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

The committee formally confirmed the minutes of the last (i.e., Fifteenth) meeting of the Medical Laboratory Instruments Sectional Committee (MHD-10), held on 20 October 2022, Friday via Video Conferencing (Webex).



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

**2.1** The committee noted current composition of the Medical Laboratory Instruments Sectional Committee (MHD-10).

## **ITEM 3 ISSUES ARISING OUT OF PREVIOUS MEETING**

**3.1** Committee noted the request of MHD-12 Sectional committee regarding transfer of the Indian Standards/Documents, given at Table 1, to MHD-10 Sectional Committee.

**3.2** The committee deliberated and decided that the Indian Standards given at Table 1 does not pertain to MHD-10.

**3.3** The committee further clarified that MHD-10 is dealing with glassware and instruments used in Medical Laboratories and the subjects under discussion pertain to the glassware on the clinical side. It was suggested that MHD-12 may incorporate the expertise from the relevant field instead of transferring the subjects to MHD-10.

**3.4** After thorough deliberation, the committee decided to revert the 12 subjects given in Table 1 back to the MHD-12 Sectional Committee

<b>Sl No.</b>	<b>IS number</b>	<b>IS title</b>
1)	IS 1108 : 1975	Specification for pharmaceutical glass containers (Second Revision)
2)	IS 1984 (Part 2) : 2003/ISO 8362-4 : 1989	Injection containers for injectable and accessories Part 2 injection vials made of moulded glass (Second Revision)
3)	IS 3423 : 1973	Specification for glass containers for transfusion fluids (First Revision)
4)	IS/ISO 8536-1 : 2011/ ISO 8536-1:2011	Infusion equipment for medical use Part 1 Infusion glass bottles
5)	IS 9824 (Part 1) : 1996	Transfusion equipment for medical use - Specification Part 1 glass transfusion bottles closures and caps (First Revision)
6)	IS/ISO 11418-3 : 2016/ ISO 11418-3 : 2016	Containers and Accessories for Pharmaceutical Preparations Part 3 Screw-Neck Glass Bottles Veral for Solid and Liquid Dosage Forms



- 7) IS/ISO 11418-7 : 2016 Containers and Accessories for Pharmaceutical Preparations Part 7 Screw-Neck Vials Made of Glass Tubing for Liquid Dosage Forms
- 8) IS/ISO 13926-1 : 2018 Pen systems Part 1 Glass cylinders for pen-injectors for medical use
- 9) IS 15110 : 2002 Veterinary thermometers mercury - In - Glass type – Specification
- 10) IS 15113 : 2002 Clinical electrical thermometers with maximum device – Specification
- 11) - Blood Collection Monitor
- 12) - Blood Tube Sealer

#### **ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR FINALIZATION**

The committee noted Item No. 4 of the agenda.

#### **ITEM 5 DRAFT STANDARD/ AMENDMENT FOR APPROVAL FOR APPROVAL FOR WIDE CIRCULATION**

The committee decided to share the latest version of ISO standard **ISO 17593 : 2022** '*Clinical laboratory testing and in vitro medical devices —Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy*' with the following members for their perusal and comments for 03 weeks.

- a) All India Institute of Medical Sciences, New Delhi; **Dr Tushar Sehgal**
- b) Association of Indian Medical Device Industry, New Delhi; **Shri Rakesh Jain**
- c) Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune; **Dr. Chandrashekhar G. Raut**
- d) Kalam Institute of Health Technology, Vishakhapatnam; **Smt. Sushmita Roy**

*In absence of comments, the ISO 17593 : 2022 Standard will be wide circulated for 30 days.*

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

The Committee noted the information provided at Item 6 of the agenda.

#### **ITEM 7 NEW SUBJECTS**

The Committee noted the information provided at Item 7 of the agenda.

#### **ITEM 8 PRESENT PROGRAM OF WORK**



Minutes for the Sixteenth meeting of the Medical Laboratory Instruments  
Sectional Committee, MHD-10  
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The Committee noted the present *Program of Work* and decided to share the following Draft Indian Standards and the comments received thereof within the committee for perusal. It was decided that these comments will be discussed in the next meeting of the committee for their resolution.

**MHD10 (13650)** Biological Safety Cabinet – Class I

**MHD10 (13651)** Biological Safety Cabinet – Class II

**MHD10 (16151)** Rotary Shaker – Specification

Following members have been identified to resolve the comments.

- a) Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune; **Dr. Chandrashekhhar G. Raut**
- b) Kalam Institute of Health Technology, Vishakhapatnam; **Smt. Sushmita Roy**
- c) Bharati Vidyapeeth Medical College, Pune; **Col Mahadevan Kumar**

**ITEM 9 DATE AND PLACE OF NEXT MEETING**

The date and place of next meeting will be decided in consultation with the Hon'ble Chairman,  
MHD-10

**ITEM 10 ANY OTHER BUSINESS**

The meeting concluded with closing remarks of the Hon'ble Chairman.