

BUREAU OF INDIAN STANDARDS
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
(MHD)

MINUTES

Sectional Committee	Meeting No:	Date, Day & Time
Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12)	14	12 March 2024 Tuesday 11:00 AM
<i>via Webex platform</i> Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m21f71115c889cdb5c5f7d4f794c2f966 Meeting Number: 2521 668 2718 Password: Mhd@12		
Chairperson Lt Gen Sunil Kant (Retired)	Member Secretary Ms. Harshada Ganesh Kadam, Sc-B	

ITEM 0 GENERAL

Member Secretary greeted the members present in the meeting The meeting commenced with the introduction of the members.

The list of participants is given in Annexure A.

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

Member Secretary of MHD 12, appreciated the members for sparing their valuable time to attend the 14th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee. She also expressed her gratitude towards the chairperson and all committee members for their continuous support in the standardization activity.

0.2 OPENING REMARKS BY CHAIRPERSON

Lt-Gen. Sunil Kant complimented BIS in organizing the hybrid meeting and being a leading force

in the formulation of Indian Standards. He was highly appreciative of the efforts of the Member Secretary in organizing timely meetings of BIS and the guidance and support of the Head MHD Mr. Unnikrishnan in the activities of the Sectional Committee. He also emphasized that the timely adoption of ISO standards is an important area of the Hospital Equipment and Surgical Disposable Products Sectional Committee.

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The Committee formally confirmed the minutes of the 13th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee MHD12 held on 10 Nov 2023 via hybrid mode.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

- 2.1 The Committee noted the contents of Item 2.1 of the agenda.
- 2.2 The Committee noted the contents of Item 2.2 of the agenda.
- 2.3 The Committee noted the contents of Item 2.3 of the agenda.
- 2.4 The Committee noted the contents of Item 2.4 of the agenda.
- 2.5 The Committee noted the contents of Item 2.5 of the agenda.
- 2.5.1 The Committee noted the contents of Item 2.5.1 of the agenda.

2.6.: The committee deliberated on the co-option request received from the following organizations:

Sl. No.	Organization	Committee Decision
1.	Medtronic India Pvt Ltd, Gurugram	The Committee requested the MS for CV of nominees for further deliberation.
2.	Medical Gloves Assosiation-I&E	
3.	Helthium Pvt Ltd	

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The Committee noted the contents of Item 3.1 of the agenda

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The Committee noted the contents of Item 4.1 of the agenda

ITEM 5 DRAFT UNDER PREPARATION

5.1 The Committee noted the contents of Item 5.1 of the agenda.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 The Comments received on the following published Indian standard were deliberated:

Sr No	IS Number	Title	Committee deliberation
1	IS 4148 :1989	Surgical rubber gloves – Specification	The Committee deliberated and decided to take inputs from the user's point of view for further deliberation on the Standards.

ITEM 7 NEW SUBJECTS

7.1 The Committee noted the contents of Item 7.1 of the agenda

ITEM 8 TECHNICAL ISSUES

8.1 The comments received on the following documents were discussed by the committee.

Sl. No.	Document No.	Title	Committee decision
1	MHD/12/19717	Blood donor couch	The Committee deliberated and decided to circulate the received comments on documents to committee members for a period of 20 days.
2	MHD/12/24231	Specification for Vaccine carrier - General requirements and test method	The Committee deliberated and decided to circulate the received comments on documents to committee members for a period of 20 days.
3	MHD/12/24230	Specification for refrigerator or combined refrigerator and water pack freezer intermittent mains powered - compression cycle- general requirement and test method	The Committee deliberated and decided to circulate the received comments on documents to committee members for a period of 20 days. The Committee requested NCCVMRC to submit the list of manufacturers of refrigerator or combined refrigerator and water pack freezer
4.	MHD/12/23337	Single-use Sterile Rubber Surgical Gloves-Specification	The Comments received were discussed & committee decided to adopt the standards aligned with ISO 10282:2023 The Committee also advised to take up the comments with ISO for further deliberation.

ITEM 9. INTERNATIONAL ACTIVITIES

- 9.1 The Committee noted the contents of Item 9.1 of the agenda.
- 9.2 The Committee noted the contents of Item 9.2 of the agenda.
- 9.3 The Committee noted the contents of Item 9.3 of the agenda.
- 9.4 The Participation in ISO/TC 198 /WG2: Radiation sterilization, Dr Sanjay Rajput has shown interest in working as an expert in WG2 .

The committee advised Dr Sanjay Rajput to share the CV with MS & committee requested to MS to circulate the CV for the Committee members for a period of 14 days.

ITEM 10. PROGRAMME OF WORK

- 10.1 The Committee noted the contents of Item 10.1 of the agenda.

10.2 Review of Indian Standards (Pre-2000 Standards)

- 10.2.1 The Committee noted the contents of Item 10.2.1 of the agenda.
- 10.2.2 The Committee noted the contents of Item 10.2.2 of the agenda.
- 10.2.3 The Committee noted the contents of Item 10.2.3 of the agenda.
- 10.2.4 The Committee noted the contents of Item 10.2.4 of the agenda.
- 10.2.5 The Committee decided to withdraw the following Indian Standards as decided by panel:

Sr. No	IS No	Title
1	IS 11400 : 1985	Specification for hypodermic syringes, interchangeable type for general purposes
2	IS 1108 : 1975	Specification for pharmaceutical glass containers (Second Revision)
3	IS 10985 : 1984	Specification for needle, acupuncture
4	IS 7455 : 1974	Specification for sterilizer, pressure, hot and cold water

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

- 10.3.1 The Committee noted the contents of Item 10.3.1 of the agenda.
- 10.3.2 The Committee noted the contents of Item 10.3.2 of the agenda.
- 10.3.3 The Committee deliberated and decided to review the standards in the 2024-25 quarter. The list is attached at Annexure B.

ITEM 11 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

- 11.1 The Committee noted the contents of Item 11.1 of the agenda.

ITEM 12 STANDARD TO BE WITHDRAWN

12.1 The Committee deliberated and decided to withdraw the standard. Consider the Minamata convention notification and phase out such product standards and establish alternative standards wherever required.

S.No.	IS No.	Title	Scope
1	IS 15110	Veterinary thermometers, mercury - In - Glass type – Specification.	This standard covers maximum self-registering, mercury-in-glass reusable thermometers used for measuring animal body temperatures.

ITEM 13 STANDARD FOR TRANSFER TO OTHER COMMITTEE

13.1 The Committee deliberated and decided to transfer the standard from MHD 12 to MHD 15. Consider the Scope of standard which is more relevant with MHD 15.

S.No.	IS No.	Title	Scope
1	IS 15113	Clinical electrical thermometers with maximum device - Specification	1.1 This standard specifies the metrological and technical requirements for clinical electrical thermometers with a maximum device. Such instruments are designed to measure human or animal body temperature. 1.2 This specification applies to battery-powered instruments which provide a digital indication of temperature

ITEM 14 ANY OTHER BUSINESS

14.1 The Committee noted the contents of Item 14.1 of the agenda.

14.2 The Committee noted the contents of Item 14.2 of the agenda.

14.3 The Committee decided to incorporate the changes throughout the Amendment, whenever the amendment is taken up.

14.4 The Committee deliberated and requested MS for the CV of nominees for further deliberation.

14.5 The Committee deliberated and decided to adopt the following ISO Standards.

Sr No	ISO	Year	Title
1	ISO 7886-4	2018	Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature
2	ISO 11608-2	2022	Needle-based injection systems for medical use — Requirements and test methods — Part 2: Doubleended pen needles

ITEM 15 DATE AND PLACE OF NEXT MEETING

15.1 The Committee accepted the annual meeting calendar and decided to have the next meeting on 29th May 2024 according to the meeting calendar.

Quarter of FY	Q1 2024-25	Q2 2024-25	Q3 2024-25	Q4 2024-25
Month	May	September	December	March
Proposed Date	29 th May 2024 Wednesday	28 th Aug 2024 Wednesday	27 th Nov 2024 Wednesday	5 th Feb 2025 Wednesday

Annexure A
(Item 0)

Participants:

Sl.No.	Organization	Name
1)	IN INDIVIDUAL CAPACITY	Lt Gen Sunil Kant (<i>Chairperson</i>)
2)	3M India Limited, Bengaluru	Mr. Kulveen Singh Bali
		Dr. Prabha Hegde
3)	Asia Pacific Medical Technology Association (APACMed), Gurugram	Mr. Parveen Jain
4)	Association of Indian Medical Device Industry, New Delhi	Mr. Ravi Abraham
		Mr. Rajiv Nath
		Mr. Kamlesh R Shah
5)	B Medical Systems India Private Limited, New Delhi	Mr. Kishor Tukaram Kaniche
		Mr. Anshuman Tuli
		Mr. Ketan Gayawal
6)	B. Braun Medical India Private Limited, New Delhi	Mr Vivek Veerbhan
		Ms Ishita Dhingra
7)	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan
8)	E.I. DuPont India Private Limited, Gurugram	Mr. Vishnu Shankar Vyas
9)	ESIC Dental College and Hospital, Delhi	Dr. Mansi Atri
10)	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Mr. Praveen Kumar Sharma
11)	Indian Rubber Gloves Manufacturers Association , New Delhi	Mr. Naveen Kumar Reddy
12)	Johnson and Johnson Private Limited, Mumbai	Ms. Himani Gupta
13)	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Amit Sharma
		Mr. Mohan Ragul
14)	Kanam Latex India Private Limited, Kottayam	Mr. Abraham C. Jacob
		Mr. Donald S.K.
15)	Microtrol Sterilisation Services Private Limited, Mumbai	Mr. Bansidhar S. Dhurandhar
16)	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)	Mr. Hitesh Kumar
		Mr. Shivley Sageer (<i>Physically</i>)
17)	Shriram Institute for Industrial Research, Delhi	Dr. Sanjay Rajput
18)	Stryker India Private Limited, Gurugram	Mr. Sanjeev Gautam

19)	Terumo Penpol Private Limited, Thiruvananthapuram	Mr. Manoj A.
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BIS Directorate General: -

Sr No.	Name	Designation
1)	Ms. Harshada Ganesh Kadam	Scientist-B/Assistant Director, MHD, Bureau of Indian Standards

Annexure B
(Item No 10.3.3)

S.No.	IS Number	IS Title	Due Date
1.	IS 12227: 2020 ISO 8537: 2016	Sterile Single-Use Syringes, With or Without Needle, for Insulin (Second Revision)	March, 2025
2.	IS 3120: 1999	Baby incubators - Specification (Second Revision)	April, 2024
3.	IS 3829 (Part 1): 1999	Specification for steam sterilizers: Part 1 horizontal cylindrical and horizontal rectangular steam sterilizers, pressure type (For Hospital and Pharmaceutical Use) (Second Revision)	April, 2024
4.	IS 3993: 1993	Trays, instruments - Specification (Second Revision)	December, 2024
5.	IS 3994: 1993	Bowls, wash - Specification (Second Revision)	December 2024
6.	IS 5022: 1989	Sterilizer, instruments, table model (Third Revision)	May, 2024
7.	IS 5630: 1994	Cribs (Cradles), maternity - Specification (First Revision)	April, 2024
8.	IS/ISO 10555-4: 2013	Sterile, single - Use intravascular catheters: Part 4 balloon dilatation catheters	December, 2024