

BUREAU OF INDIAN STANDARDS

HOSPITAL EQUIPMENT AND SURGICAL DISPOSAL SECTIONAL COMMITTEE.
MHD 12

MINUTES

Sectional Committee		Meeting No:	Date, Day & Time
Hospital Equipment And Surgical Disposable Products Sectional Committee (MHD 12)		13	10 Nov 2023 04:00 pm
Chairperson Lt Gen Sunil Kant	Member Secretary Ms Harshada Ganesh Kadam		

ITEM 0 GENERAL

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

The list of participant is given in [Annexure A.](#)

0.1 WELCOME ADDRESS

Member Secretary of MHD 12, appreciated the members for sparing their valuable time to attend the meeting. She also expressed her gratitude towards the chairperson for his 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 CONFORMATION OF MINUTES OF LAST MEETING

As per Item 1 of the agenda, the committee formally confirmed the minutes of the 12th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee MHD12 held on 04 Sep 2023.

ITEM 2 SCOPE AND COMPOSITION OF HOSPITAL EQUIPMENT AND SURGICAL DISPOSABLE PRODUCTS SECTIONAL COMMITTEE.

2.1 The Committee noted the scope of the Hospital Equipment and Disposable Products Sectional Committee, MHD12 as mentioned in Item 2.1 of the agenda.

2.2 The Committee noted the composition of the Hospital Equipment and Surgical Disposable Sectional Committee.

2.3 The Committee noted the contents of Item 2.3 of the Agenda

2.4 The Committee deliberated and approved the new nominations for the sectional committee as per the agenda Items 2.4 and 2.5.

ITEM 3 DRAFT INDIAN STANDARDS UNDER PRINT

The Committee noted the contents of Item 3 of the Agenda.

ITEM 4 DRAFT INDIAN STANDARD FOR FINALISATION.

4.1 The Committee deliberated on Agenda Item 4.1 and decided to circulate the WC document for a period of 15 days. If technical comments are received on the Doc, then it may be taken up in the next sectional committee meeting. If no comments are received, standards may be finalized through consultation with the chairperson.

ITEM 5 DOCUMENT FOR APPROVAL FOR WIDE CIRCULATION

The Committee noted the contents of Item 5 of the Agenda.

ITEM 6 DRAFT UNDER PREPARATION

The Committee noted the contents of Item 6 of the Agenda.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

The Committee noted the contents of Item 7 of the agenda.

ITEM 8 NEW SUBJECT

The Committee noted the contents of Item 8 of the Agenda

ITEM 9 TECHNICAL ISSUES

The Committee deliberated and decided to drop the following documents .same will be circulated as a fresh WC Documents

Sr No	Doc No	Title
1	MHD/12/14451	Ice -lined Refrigerator (ILR) for temperature range of -15c to - 25c
2	MHD/12/13693	Vaccine Carriers
3	MHD/12/14449	Walk in cooler

ITEM 10 INTERNATIONAL ACTIVITIES

10.1 The committee noted the content of Item 10.1 of the agenda.

10.2 The committee noted the content of Item 10.2 of the agenda.

10.3 The Committee decided to adopt the ISO Standards and amendments as well as additional parts whose earlier parts are already adopted and mentioned in Annexure B and may thus be adopted.

a) The committee deliberated and approved new nominations for ISO WG groups,

The working group of ISO/TC 76 are given below:

S. No	Working group	Title	Approved List of members
1	ISO/TC 76/WG 1	Soft containers for blood, blood components and par-enteral; Infusion, transfu-sion, and blood processing equipment	1) Sh. Manoj A, Terumopenpol Pvt. Ltd., Thiruvananthapuram m 2) Dr. Aseem Sahu, CDSCO, New Delhi 3) Ashok Kumar, Asian Pacific Medical Technology Association, Gurugram 4) Lt Gen Sunil Kant, Chairperson, MHD 12 5) Harshada Kadam, BIS
2	ISO/TC 76/WG 2	Rigid container systems and related accessories for par-enteral and injectables	1) Lt Gen Sunil Kant, Chairperson, MHD 12 2) Harshada Kadam, BIS
3	ISO/TC 76/WG 4	Elastomeric parts and com-ponents and related second-ary packaging components	1) Dr. Aseem Sahu, CDSCO, New Delhi 2) Lt Gen Sunil Kant, Chairperson, MHD 12 3) Ashok Kumar, Asian pacific Medical Technology Association, Gurugram 4) Harshada Kadam, BIS

b) The working group of ISO/TC 84 are given below:

S. No	Working group	Title	Approved List of members
1	ISO/TC 84/WG 3	Needle-based injection systems - Injector, container and pen needle	1)Sh. Narendra Kumar Jain Iscon Surgicals, Jodhpur 2)Sh. Rajiv Nath, AIMED 3) Lt Gen Sunil Kant, Chairperson MHD 12 4) Harshada Kadam, BIS
2	ISO/TC 84/WG 8	Sharps containers	1)Sh. Rajiv Nath, AIMED 2) Sh. P K Sharma, AIMED 3) Lt Gen Sunil Kant, Chairperson MHD 12 4) Harshada Kadam, BIS
3	ISO/TC 84/WG 9	Catheters	1) Lt Gen Sunil Kant, Chairperson MHD 12 2) Harshada Kadam, BIS
4	ISO/ TC 84/ WG 10	Needles	1) Lt Gen Sunil Kant, Chairperson MHD 12 2) Harshada Kadam, BIS 3) P. K Sharma Aimed
5	ISO/TC 84/WG 11	Syringes	1)Sh. Narendra Kumar Jain IsconSurgicals, Jodhpur 2) Sh. Rajiv Nath, AIMED 3) Lt Gen Sunil Kant, Chairperson MHD 12 4) Harshada Kadam, BIS
6	ISO/TC 84/WG 16	Drug delivery system requirements for pediatrics and other demographics	1) Lt Gen Sunil Kant, Chairperson MHD 12 2) Harshada Kadam, BIS
7	ISO/TC 84/WG 17	Specification and demonstration of reliability of single-use drug delivery systems	1) Lt Gen Sunil Kant, Chairperson MHD 12 2) Harshada Kadam, BIS

c) The list of working groups ISO/TC 198 is given below:

Sr No	Working Groups	Title	Approved list of members
1	ISO/TC 198/WG 1	Industrial ethylene oxide sterilization	1)Sh. Bansi Dhurandhar, Microtrol Sterilisation Services Pvt. Ltd. (Mumbai) 2) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore 3) Lt Gen Sunil Kant , Chairperson MHD 12 4) Harshada kadam, BIS 5) Mr Ashok Kumar, Asian pacific medical technology association, gurugram
2	ISO/TC 198/WG 2	Radiation sterilization	1)Sh. Bansi Dhurandhar, Microtrol Sterilisation Services Pvt. Ltd. (Mumbai) 2) Lt Gen Sunil Kant chairperson, MHD 12 3) Mr Ashok Kumar, Asian pecific Medical Technology Association, gGurugram 4) Harshada Kadam, BIS

3	ISO/TC 198/WG 3	Moist heat sterilization	1) Lt Gen Sunil kant, Chairperson MHD 12 2) Mr MnojA, terumo penpol private limited 3) Harshada Kadam, BIS 4) Mr Ashok Kumar, Asian pecific medical technology association , Gurugram
4	ISO/TC 198/WG 4	Biological indicators	1) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore 2) Lt Gen Sunil Kant , Chairperson MHD 12 3)Mr Ashok Kumar, Asian pecific medical technology association , Gurugram 4) Harshada Kadam, BIS
5	ISO/TC 198/WG 5	Terminology	1) Lt Gen Sunil Kant , Chairperson MHD 12 2)Mr Ashok Kumar, Asian pecific medical technology association , gurugram 3) Harshada Kadam, BIS
6	ISO/TC 198/WG 6	Chemical indicators	1)Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore 2) Lt Gen Sunil Kant , Chairperson MHD 12 3)Mr Ashok Kumar, Asian pecific medical technology association , gurugram 4) Harshada Kadam, BIS
7	ISO/TC 198/WG 7	Packaging	1)Sh. Vishnu Vyas, Dupont, Gurgaon 2) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore 3) Lt Gen Sunil Kant , Chairperson MHD 12 4) Harshada Kadam, BIS
8	ISO/TC	Microbiological	1) Lt Gen Sunil Kant , Chairperson MHD 12

	198/WG 8	methods	2)Mr Ashok Kumar, Asian pacific medical technology association , gurugram 3) Harshada Kadam, BIS
9	ISO/TC 198/WG 9	Aseptic processing	1) Lt Gen Sunil Kant , Chairperson MHD 12 2)Mr Ashok Kumar, Asian pecific Medical Technology Association, gurugram 3) Harshada Kadam, BIS
10	ISO/TC 198/WG 12	Information for reprocessing of re serializable devices	1) Lt Gen Sunil Kant , Chairperson MHD 12 2) Harshada Kadam, BIS
11	ISO/TC 198/WG 13	Washer- disinfectors	1) Lt Gen Sunil Kant , Chairperson MHD 12 2) Harshada Kadam, BIS

- The Committee deliberated on ISO/TC 45 /SC 4/WG 5 ‘Gloves and other latex products’ and approved the nominations for WG 5 experts Ms Harshada Kadam and Lt Gen Sunil Kant.
- The Committee approved the ISO/TC 84 AG experts: Ms Harshada Kadam and Lt Gen Sunil Kant

ITEM 11 PROGRAMME OF WORK

11.1 The Committee noted the content of Item 11.1 of the agenda.

11.2 The Committee deliberated and decided to make a panel for pre-2000 standards and as per priority will be taken up for revision in the panel.

- As per the agenda Items 11.2.2 and 11.2.3, the list of reviewed standards may be circulated in committee for a period of 15 days. If technical comments are received on the Doc, then it may be taken up in the pre-2000 panel. If no comments are received, standards may be finalized through consultation with the chairperson and pre-2000 panel members.

11.3 The Committee deliberated and decided to take up the review of Indian standards (as per 5-year cycle) as mentioned in Annexure C.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 The Committee noted the content of Item 12.1 of the agenda.

ITEM 13 SUBJECT TO BE TRANSFER

13.1 The Committee decided to transfer IS 15110 to MHD 13 because IS 15110 scope comes under MHD 13.

The Committee decided to transfer IS 15113 to MHD 15 because IS 15113 scope comes under MHD 15.

ITEM 14 DATE AND PLACE OF NEXT MEETING

14.1 The Committee decided to conduct the next physical meeting after Jan 2024 the date of the meeting will be scheduled.

ITEM 15 ANY OTHER BUSINESS

15.1 The Committee deliberated and approved the R &D project proposed for the Revision of hospital furniture standards.

Annexure A

LIST OF PARTICIPANTS

PARTICIPENTS:

S.No.	Organization	Members Present
1.	In Individual Capacity	Lt Gen Sunil Kant
2.	3M India Limited, Bengaluru	Ms. Dr. Prabha Hegde
3.	Association of Indian Medical Device Industry, New Delhi	Mr. Shri Kamlesh R. Shah
4.	Association of Indian Medical Device Industry, New Delhi	Mr. Ravi Abraham
5.	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri R. Ashok Kumar(<i>physically</i>)
6.	B. Braun Medical India Private Limited, New Delhi	Mr. Arihant Jain
7.	Boston Scientific India Private Limited, Gurugram	Mr. Prashanth Prabhakar
8.	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan Dr. Aseem Sahu Shri Pradeep
9.	Hindustan Syringes and Medical Devices Limited, Ballabgarh, Faridabad	Mr P K Sharma (representative)
10.	Indian Institute of Technology Delhi, New Delhi	Mr. Aarat p Kalra
11.	Indian Rubber Gloves Manufacturers Association , New Delhi	Mr. Naveen Kumar Reddy
12.	Indian Rubber Gloves Manufacturers Association , New Delhi	Mr. Harpreet Singh(<i>physically</i>)
13.	Indian Rubber Gloves Manufacturers Association , New Delhi	Manmohan Singh Gulati(<i>physically</i>)
14.	Indian Rubber Gloves Manufacturers Association , New Delhi	Vikas Anand(<i>physically</i>)
15.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Amit Sharma
16.	Lady Irwin College, New Delhi	Ms. Dr. Sheetal Chopra

17.	Post Graduate Institute of Medical Education and Research, Chandigarh	Ms. Dr. Navneet Dhaliwal
18.	Terumo Penpol Private Limited, Thiruvananthapuram	Mr. Manoj A.
19.	NCCVMRC-NIHFW	Er. Shivley Sageer(<i>physically</i>)(Invitee)

BIS GENERAL DIRECTORATES:

1	Ms.Harshada Kadam	Scientist-B, MHD. BIS
2	Mr Prashant Vinjamuri	Scientist-C, MHD.BIS
3	Mr. Chandan Kumar	Scientist-C, MHD.BIS

Annexure B

S.No.	ISO No.	Title
1.	ISO 8536-2:2023	Infusion equipment for medical use — Part 2: Closures for infusion bottles
2.	ISO 8536-3:2009	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles
3.	ISO 8536-3:2009/Amd 1:2022	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles — Amendment 1
4.	ISO 8536-5:2004	Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed
5.	ISO 8536-6:2016	Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles
6.	ISO 8536-7:2009	Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles
7.	ISO 8536-8:2015	Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus
8.	ISO 8536-9:2015	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment
9.	ISO 8536-10:2015	Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment
10	ISO 8536-11:2015	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment
11	ISO 8536-12:2021	Infusion equipment for medical use — Part 12: Check valves for single use
12	ISO 8536-13:2016	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact
13	ISO 8536-14:2016	Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact
14	ISO 8536-15:2022	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use
15	ISO 8536-15:2022/Amd 1:2023	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use — Amendment 1

16	ISO 11135:2014/A md 1:2018	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices — Amendment 1: Revision of Annex E, Single batch release
17	ISO 13408-3:2006	Aseptic processing of health care products — Part 3: Lyophilization
18	ISO 13408-4:2005	Aseptic processing of health care products — Part 4: Clean-in-place technologies
19	ISO 13408-5:2006	Aseptic processing of health care products — Part 5: Sterilization in place
20	ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems
21	ISO 13408-7:2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products
22	ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification
23	ISO 7886-2:2020	Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps
24	ISO 11070:2014/A md 1:2018	Sterile single-use intravascular introducers, dilators and guidewires — Amendment 1
25	ISO 239071:2019	Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers
26	ISO 239072:2019	Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers
27	ISO 23908:2011	Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

Annexure C

S.No.	IS Number	IS Title	Due Date
1	IS 10654: 2018 ISO 7864 : 2016	Sterile hypodermic needles for single use -Requirements and test methods (Fourth Revision)	December, 2023
2	IS 12173 : 1987	Specification for cervical halter	September, 2023
3	IS 12430 : 1987	Safety code for installation, servicing maintenance and of sterilizers	July, 2023
4	IS 7081 : 1973	Specification for stool, revolving, for hospital use	March, 2024
5	IS 7350 : 1974	Specification for needles, spinal	September, 2023
6	IS 7387 : 1974	Needle, Biopsy, Liver, Silverman's Pattern	August, 2023
7	IS 9824 (Part 1) : 1996 ISO 1135-1	Transfusion equipment for medical use - Specification: Part 1 glass transfusion bottles,closures and caps (First Revision)	October, 2023
8	IS/ISO 11607 : 2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems (First Revision)	March, 2024
9	IS/ISO 11607 : 2019	Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements forForming Sealing and Assembly Processes(First Revision)	March, 2024
10	IS/ISO 8536-4 : 2019	Infusion equipment for medical use Part 4: Infusion sets for single use gravity feed	March, 2024
11	IS/ISO 3826-1 : 2019	Plastics collapsible containers for human bloodand blood components Part 1 Conventional containers First Revision	March, 2024
12	IS/ISO 11737-2 : 2019	Sterilization of health care products Microbiological methods Part 2 Tests of sterility performed in the definition validationand maintenance of sterilization process	March, 2024