

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
Bureau of Indian Standards

MINUTES

**21st Meeting: Obstetric and Gynaecological Instruments and Appliances Sectional
Committee, MHD-03**

Sectional Committee		Meeting No:	Date & Time
Obstetric and Gynecological Instruments and Appliances Sectional Committee, (MHD 03)		21	30 April, 2024 02:30 PM
Chairperson Dr. Suneeta Mittal, In personal Capacity	Member Secretary Gurpreet Kaur, Sc-C, MHD, BIS		

The list of attendees is given at **Annexure-A**.

ITEM 0 WELCOME ADDRESS AND OPENING REMARKS

0.1 Opening Remarks by Chairperson

Dr. Suneeta Mittal, Chairperson (MHD 03) extended a warm welcome to the members of Obstetric and Gynaecological Instruments and Appliances Sectional Committee, MHD-03. She appreciated the attendance of the members and further encouraged the members for active participation in the meetings and standard formulation activities of MHD 03.

0.2 Welcome address by Head (MHD)

Shri A R Unnikrishnan, Scientist-G & Head (MHD) welcomed all the members to the 21st meeting of MHD 03. He informed them of the process reforms that were being undertaken by BIS to monitor and strengthen the efficiency index of all the TCs under BIS. He appreciated the members for their contribution to this committee and highlighted the importance of their attendance in the meetings.

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The committee confirmed the minutes of the last (20th) meeting held on 12th December, 2023 through WebEx.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The committee took note of the modified scope as approved in the 17th meeting of MHDC.

2.2 The committee noted the composition of sectional committee (MHD 03) and the attendance of member organizations provided at Annexure-A of the agenda.

2.3 The committee noted the information at item 2.3. It was decided to seek nominations for alternate members from the following organizations:

Sl. No.	Organisation
1.	Indian Institute of Technology, Kharagpur
2.	Office of Development Commissioner (MSME), New Delhi

2.4 Chemco Industries Pvt. Ltd., Mumbai vide letter dt. 26-04-2024 proposed to have another WG meeting prior to the wide circulation of the document on Menstrual Cups. During the meeting, it was proposed to hold the next WG meeting in the 2 weeks' time, tentatively 3rd week of May. The updated draft can then be subsequently put up for the decision of wide circulation.

ITEM 3 DRAFT STANDARDS FOR FINALIZATION

The Committee noted the documents for revision of pre 2000 standards which were yet to complete the wide circulation period. In case no comments received after the last date, the documents may be finalized in consultation with the Chairperson:

Sl. No.	Document No.	Title	Last date for comments
1.	MHD 03 (25156)	Uterine Sound - Specification (<i>Second revision of IS 5829: 1982</i>)	02 May 2024
2.	MHD 03 (25157)	Anterior Vaginal Wall Retractor Sims Pattern - Specification (<i>First revision of IS 5849: 1970</i>)	02 May 2024
3.	MHD 03 (25158)	Vaginal Speculum Cusco's Pattern - Specification (<i>First revision of IS 5906: 1970</i>)	02 May 2024
4.	MHD 03 (25159)	Suction Type Uterine Curette - Specification (<i>First revision of IS 6111: 1971</i>)	02 May 2024
5.	MHD 03 (25160)	Mucus Sucker – Specification (<i>First revision of IS 6373: 1971</i>)	02 May 2024
6.	MHD 03 (25271)	Sims Pattern Double-Ended Sharp Uterine Curette - Specification (<i>First Revision of IS 6499: 1971</i>)	15 May 2024
7.	MHD 03 (25272)	Cannula Intra-Uterine Hysterosalpingography - Specification (<i>First Revision of IS 10156: 1982</i>)	15 May 2024
8.	MHD 03 (25273)	Laposcopic Trocar And Cannula Specification (<i>First Revision of IS 12271: 1988</i>)	15 May 2024
9.	MHD 03 (25274)	MTP Suction Apparatus Specification Part 1 Manually Operated (<i>Third Revision of IS 7080 (Part 1): 1992</i>)	15 May 2024
10.	MHD 03 (25275)	MTP Suction Apparatus Specification Part 2 Electrical-Cum-Manually Operated (<i>Second Revision of IS 7080 (Part 1): 1992</i>)	15 May 2024

ITEM 4 DRAFT STANDARDS FOR APPROVAL FOR WIDE CIRCULATION

The Committee decided to adopt *ISO/TS 23148: 2024 Compatibility of lubricants with synthetic male condoms*. The draft to be widely circulated for a period of one month.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The committee noted the composition of working groups for formulation of the drafts currently under preparation. The composition was updated and new experts were included as follows:

Subject	WG composition
<u>MHD/03/19202 (P draft)</u> <i>Menstrual Cups – Specification</i>	Mr Gaurav Saraogi, Chemco Industries (<i>Convener</i>) Dr Suneeta Mittal, Chairperson Dr K Sivakumar, In personal capacity Dr Malabika Roy, In personal Capacity Mr Mukund R, HLL Lifecare Dr Minakshi Rohilla, PGIMER, Chandigarh
<u>MHD/03/20629 (P draft)</u> <i>Intrauterine Contraceptive Devices – Copper-T (380A) – Specification</i>	Dr K Sivakumar, In personal capacity (<i>Convener</i>) Dr Suneeta Mittal, Chairperson Mr Mukund R, HLL Lifecare Experts from Corporate Channels India Ms Sayali Umesh Warde, CDTL Mumbai Mr Ajit Raje, Pregna International, Pune Mr Anupam Rai, SMB Corporation
<u>MHD/03/21249 (P draft)</u> <i>LNG IUD – Specification</i>	Mr Mukund R, HLL Lifecare (<i>Convener</i>) Dr Suneeta Mittal, Chairperson Dr K Sivakumar, In personal capacity Dr Malabika Roy, In personal capacity Mr Ajit Raje, Pregna International Ltd. Experts from SCTIMST, Kerala
<i>Vaginal Ring</i>	Dr Malabika Roy (<i>Convener</i>) Dr Suneeta Mittal, Chairperson Dr K Sivakumar, In personal capacity Experts from HLL, Thiruvananthapuram

5.2 The WG meeting for IUCD-Copper T(380A) to be held in the end of May 2024.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

No comments were received on published Indian Standards.

ITEM 7 NEW SUBJECTS

The Committee noted the subjects currently under formulation in MHD 03 and took the following decisions:

7.1 It was decided to circulate IS 13450 (Part 2/Sec 2): 2019 /IEC 60601-2-2: 2017 *Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance*

Section 2 High frequency surgical equipment and high frequency surgical accessories for further comments from members.

7.2 Balloon Ablation: It was decided to explore the existing standards and to check for the organizations wherever the product is still in use. It was proposed to form a new WG under MHD 03 for this purpose.

ITEM 8 TECHNICAL ISSUES

There were no technical issues to be discussed.

ITEM 9 INTERNATIONAL ACTIVITIES

9.1 The Committee approved the Indian delegation proposed at Item 9.2 of agenda to participate in the upcoming ISO/TC 157 Meetings in September, 2024 at Australia:

S. No.	Member Name	Organization
1.	Dr Suneeta Mittal	In Personal Capacity, Chairperson
2.	Dr. K. Sivakumar	In Personal Capacity (Convener, WG 14 & WG 17)
3.	Dr. Malabika Roy	In Personal Capacity
4.	Mr. Mukund R	HLL Lifecare Ltd., Thiruvananthapuram
5.	Mr. Manikantan S. A	HLL Lifecare Ltd., Thiruvananthapuram
6.	Mr P J Reddy	Indus Medicare Private Limited, Hyderabad (Convener, TG 2)
7.	Mr B. R. Mohanty	Indus Medicare Private Limited, Hyderabad
8.	Dr. Puneet Manocha	MHL Healthcare Limited, Muzaffarnagar
9.	Mr Brijj Balaji Singh	TTK Healthcare Limited, Chennai
10.	Dr. Minakshi Rohilla	PGIMER, Chandigarh
11.	Ms. Sukhada Ajay Navaratne	Central Drugs Testing Laboratory, Mumbai
12.	Mr Girish R Shah	SMB Corporation of India, Mumbai
13.	Mr Anupam Rai	SMB Corporation of India, Mumbai
14.	Gurpreet Kaur Bhombra	BIS, New Delhi (Member Secretary, MHD 03)

9.2 The Committee approved for the nomination of experts from HLL Lifecare, Thiruvananthapuram and Member Secretary, MHD 03 in ISO/TC 338/WG 1 Safety, performance and general requirements of menstrual products.

ITEM 10 PROGRAMME OF WORK

The committee noted the present programme of work of MHD-03 and the list of pre 2000 standards due for revision. The Committee approved for wide circulation of the documents listed at Item 10.3 of agenda for a period of one month.

ITEM 11 DATE AND PLACE OF NEXT MEETING

The date of the next meeting (Q2) to be finalized in consultation with the members.

ITEM 12 ANY OTHER BUSINESS

CDTL, Mumbai raised technical issues on the document MHD/03/23554, i.e. IS 18593: 2024 (Modified adoption of ISO 7439: 2023) which is under print. The technical issues to be taken up for the review of relevant stakeholders. In case of any further technical changes/modifications required, an amendment may be issued to IS 18593: 2024.

The meeting concluded with a vote of thanks to honourable chair and all the members.

ANNEXURE-A

LIST OF ATTENDEES

S.No.	Organization	Member Name
1.	In Individual Capacity	Dr. Suneeta Mittal (Chairperson)
2.	In Personal Capacity	Dr. K. Sivakumar
3.	In Personal Capacity	Dr. Malabika Roy
4.	In Personal Capacity	Dr. Amit Sen Gupta
5.	Association of Indian Medical Device Industry, New Delhi	Mr. Pradeep Narkhede
6.	Association of Indian Medical Device Industry, New Delhi	Mr. Sumedh Kaulgud
7.	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan
8.	Central Drugs Standard Control Organization, New Delhi	Mr. Aniruddh Singh Negi
9.	Central Drugs Testing Laboratory, Mumbai	Mr. C Hariharan
10.	Central Drugs Testing Laboratory, Mumbai	Ms. Sayali Umesh Warde
11.	Central Drugs Testing Laboratory, Mumbai	Ms. Sukhada Ajay Navaratne
12.	Chemco Plastic Industries Private Limited, Mumbai	Ms. Rupande Sampat
13.	Chemco Plastic Industries Private Limited, Mumbai	Mr. Gaurav Saraogi
14.	Corporate Channel India Private Limited, Mumbai	Mr. Vinod Kumat
15.	Corporate Channel India Private Limited, Mumbai	Mr. Ramnick Dagarria
16.	HLL Lifecare Limited, Thiruvananthapuram	Mr. R Mukund
17.	HLL Lifecare Limited, Thiruvananthapuram	Ms. Smitha L. G
18.	HLL Lifecare Limited, Thiruvananthapuram	Mr. Ganesh Krishnan
19.	Indus Medicare Limited, Hyderabad	Mr. P. J. Reddy
20.	Indus Medicare Limited, Hyderabad	Mr. Biswaranjan Mohanty
21.	Johnson and Johnson Private Limited, Mumbai	Mr Bhuwandeep Singhla
22.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Satyan Sharma

23.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Mohan Ragul
24.	MHL Healthcare Limited, Muzaffarnagar	Dr. Puneet Manocha
25.	Office of Development Commissioner (MSME), New Delhi	Dr Suvankar Santra
26.	Pregna International Limited, Pune	Mr. Ajit Raje
27.	Rubber Research Institute of India, Rubber Board, Kottayam	Dr. Shera Mathew
28.	SMB Corporation of India, Mumbai	Mr. Anupam Rai
29.	TTK Healthcare Limited, Chennai	Mr. Brij Balaji Singh
30.	TTK Healthcare Limited, Chennai	Mr. John Selwyn Daniel
31.	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Bindu Bajaj