

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

AGENDA

Sectional Committee		Meeting No:	Date, Day & Time
Obstetric and Gynaecological Instruments and Appliances, (MHD 03)		22	01 August, 2024 (Thursday) 3 PM onwards
Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m5d6676aaac6e6df771600abf27757cd6			
Meeting Number: 2516 420 1898			
Password: MHD3@1aug			
Chairperson	Dr Suneeta Mittal, In-personal capacity		
Member Secretary	Gurpreet Kaur, Sc-C, MHD, BIS		

ITEM 0 GENERAL

0.1 Welcome Address by Member Secretary

0.2 Opening Remarks by Chairperson

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 21st meeting of Obstetric and Gynaecological Instruments and Appliances Sectional Committee (MHD 03) held on 30th April, 2024 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD03/A2.21 dated 07 May 2024.

1.2 No comments have been received so far.

The Committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of Obstetric and Gynaecological Instruments and Appliances, (MHD 03) is as follows:

- a. To formulate Indian Standards for instruments, appliances, medical devices used in obstetrics and gynaecology and for contraception and STI Barrier prophylactics.
- b. To coordinate with the work of ISO/TC 157 'Non-systemic contraceptives and STI barrier

prophylactics.’

The Committee may please note.

2.2 The present composition of MHD 03 along with participation status of members is enclosed at [Annexure A \(Page 11-12\)](#).

The Committee may please note.

2.3 The attendance of members in Sectional Committee meetings is essential for its efficient and effective functioning. Accordingly, any member remaining absent from two consecutive meetings and/or fifty percent or more meetings of the Sectional Committee in a year will become automatically disqualified to continue as the member of the Sectional Committee.

2.4 The following members were consecutively absent in last two meetings and also were absent in fifty percent or more meetings during last year:

Sl. No.	Organisation
1.	All India Institute of Medical Sciences, New Delhi
2.	CIPET, Chennai
3.	Central Drugs Testing Laboratory, Chennai

2.4.1 The above members have become inactive by virtue of non-participation in consecutive meetings and by non-participation in fifty percent or more meetings during last year and have been removed.

The Committee may please note.

2.5 The following organizations have requested BIS for representation in the Committee:

Sl. No.	Organisation	Nomination
1.	Brahad Elastomers Pvt Ltd., Bengaluru	Mr. Shivanand Bellare

2.6 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned considering that non-industry representation should not be less than two-third of the committee composition, as far as possible.

The committee may please note and review the composition.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The following draft Indian Standards/Amendments have been sent for wide circulation:

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1.	MHD 03 (25156)	Uterine Sound - Specification (<i>Second revision of IS 5829: 1982</i>)	01 May 2024	No
2.	MHD 03 (25157)	Anterior Vaginal Wall Retractor Sims Pattern - Specification (<i>First revision of IS 5849: 1970</i>)	01 May 2024	No
3.	MHD 03 (25158)	Vaginal Speculum Cusco's Pattern - Specification (<i>First revision of IS 5906: 1970</i>)	01 May 2024	No
4.	MHD 03 (25159)	Suction Type Uterine Curette - Specification (<i>First revision of IS 6111: 1971</i>)	01 May 2024	No
5.	MHD 03 (25160)	Mucus Sucker - Specification (<i>First revision of IS 6373: 1971</i>)	01 May 2024	No
6.	MHD 03 (25271)	Sims Pattern Double-Ended Sharp Uterine Curette - Specification (<i>First Revision of IS 6499: 1971</i>)	11 May 2024	Yes
7.	MHD 03 (25272)	Cannula Intra-Uterine Hysterosalpingography - Specification (<i>First Revision of IS 10156: 1982</i>)	11 May 2024	Yes
8.	MHD 03 (25273)	Laposcopic Trocar and Cannula Specification (<i>First Revision of IS 12271: 1988</i>)	11 May 2024	No
9.	MHD 03 (25274)	MTP Suction Apparatus Specification Part 1 Manually Operated (<i>Third Revision of IS 7080 (Part 1): 1992</i>)	02 May 2024	Yes
10.	MHD 03 (25275)	MTP Suction Apparatus Specification Part 2 Electrical-Cum-Manually Operated (<i>Second Revision of IS 7080 (Part 1): 1992</i>)	12 May 2024	Yes
11.	MHD 03 (26025)	Sims Pattern Double-ended Vaginal Speculum Specification (<i>First Revision of IS 6112</i>)	27 July 2024	Yes
12.	MHD 03 (26026)	Gynaecological Instruments Forceps Uterine Vulsellum Shape and Dimensions (<i>Second Revision of IS 6114</i>)	27 July 2024	No
13.	MHD 03 (26027)	Gynaecological Instruments Forceps Uterine Tenaculum Shape and Dimensions (<i>Second Revision of IS 6112</i>)	27 July 2024	No
14.	MHD 03 (26028)	Sims Pattern Double-Ended Sharp and Blunt Uterine Curette Specification (<i>First Revision of IS 6505</i>)	27 July 2024	No
15.	MHD 03 (26029)	Suction Type Endometrial Biopsy Curette Specification (<i>First Revision of IS 6510</i>)	27 July 2024	Yes
16.	MHD 03 (26030)	Foetoscope For Foetal Heart Sounds Pinards Pattern Specification (<i>First Revision of IS 6565</i>)	27 July 2024	No
17.	MHD 03 (26031)	Obstetrics Instruments Forceps Ovum Shape and Dimensions	27 July 2024	Yes
18.	MHD 03 (26032)	Single-ended Hegars Pattern Uterine Dilators Specification (<i>First Revision of IS 6584</i>)	27 July 2024	No
19.	MHD 03 (26033)	Gynaecological Instruments Forceps Uterine Dressing Bozemans Pattern Shape and Dimensions (<i>Second Revision of IS 6589</i>)	27 July 2024	Yes
20.	MHD 03 (26034)	Curette Blunt Uterine Specification (<i>First Revision of IS 6957</i>)	27 July 2024	No

3.2 The documents where no comments have been received may be taken up for finalization.
The Committee may kindly consider.

3.3 For the documents where comments have been received, the comments are enclosed at [Annexure-B \(Page 13-15\)](#).

The Committee may kindly deliberate.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The following draft Indian Standards / Amendments are ready for wide circulation:

Sl. No.	Document No./ Standard No.	Title	Remarks
1	IS 6959: 1973	Specification for scissors embryotomy curved on flat	<i>Revision</i>
2	IS 7103: 1973	Specification for scissors episiotomy	<i>Revision</i>
3	IS 7116: 1973	Specification for forceps midwifery short	<i>Revision</i>
4	IS 7117: 1973	Specification for scissors umbilical cord	<i>Revision</i>
5	IS 7432: 1974	Clamp Myomectomy Bonney's Pattern	<i>Revision</i>

The Committee may kindly approve.

4.2 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user-friendly interface and helps faster compilation and analysis of comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.

The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The following indigenous subject drafts are under preparation by working groups of MHD 3.

Sl. No.	Project Title.
1.	Menstrual Cups – Specification
2.	Intrauterine Contraceptive Devices – Copper-T (380A) – Specification
3.	LNG IUD – Specification
4.	Vaginal Ring

The Committee may kindly note.

5.2 Commenting on P-Drafts by Members of Technical Committee

5.2.1 P-Draft is the stage where members of the concerned technical committee can support or reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the Technical Committee in a year will automatically be disqualified to continue as a member.

5.2.2 The members may examine the P-Draft document(s) whenever under circulation and offer comments as per the following options:

- (a) Agree
- (b) Agree (with comments*)
- (c) Don't agree (with comments*)
- (d) No Comments, as it is not related to my area of expertise.

5.2.3 The comments on P- Drafts shall be made only through the Standardization Portal.

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

7.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also define thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental and economic consideration.

The Committee may kindly deliberate.

7.2 The Department of Pharmaceuticals (DoP) is the nodal department for the strategic implementation of National Medical Devices Policy (NMDP), 2023. One of the action points under the roadmap for implementation of strategies under the NMDP include **adoption and expansion of Indian Standards for Medical Devices**. In this regard, DoP had constituted a committee for prioritizing the setting of Indian Standards for Medical Devices and deliberated on the list of Medical Devices where Indian Standards need to be formulated.

With reference to Obstetrics & Gynaecology, there is a need to formulate Indian Standards on the following medical devices:

Sr No	Name of Equipment
1	CTG Machine
2	Hysteroscope set with Hysteromat & office hysteroscope
3	Labor Table
4	Colposcope
5	Fetoscopy Set
6	Anti- shock garment

The Committee may kindly deliberate and decide.

ITEM 8 TECHNICAL ISSUES

There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization. The details of membership held in various Technical Committees/Subcommittees of ISO are given below:

<i>Sl. No.</i>	<i>Liaison Committee of ISO</i>	<i>Type of Membership</i>
1	ISO/TC 157 'Non-systemic contraceptives and STI barrier prophylactics	Participating Member

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO seeking votes/comments. The members should carefully examine the documents taking into consideration nation's interests and send the comments to BIS keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation. The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

The Committee may kindly note.

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 Working Groups (WGs) are established by ISO/IEC Technical Committees for specific tasks. The Experts are nominated in these WGs by BIS ('P' Member National Standards Body – NSB) to deal with specific tasks allocated to the Working Group. Persistently Inactive Experts, meaning the

absence of contributions through attendance to WG meetings or by correspondence, will be removed from the Working Groups by ISO Technical Committee. This removal of Inactive Experts would also reflect badly on the 'P' Member NSB. Therefore, participation of nominated Indian Experts at the Working Group level of ISO is of critical importance while being a part of BIS for Standards Development.

9.2.2 The following members are occupying coveted position in various Working Groups of ISO as 'Expert'.

Sl. No.	Name
1.	Dr Suneeta Mittal, Chairperson
2.	Dr K Sivakumar, In personal Capacity
3.	Dr. Malabika Roy, In personal Capacity
4.	Mr P J Reddy, Indus Medicare Private Limited, Hyderabad
5.	Mr B. R. Mohanty, Indus Medicare Private Limited, Hyderabad
6.	Ms L G Smitha, HLL Lifecare Ltd., Thiruvananthapuram
7.	Mr Mukund R, HLL Lifecare Ltd., Thiruvananthapuram
8.	Mr Ganesh Krishnan, HLL Lifecare Ltd., Thiruvananthapuram
9.	Mr Venugopal S, HLL Lifecare Ltd., Thiruvananthapuram
10.	Mr Brijj Balaji Singh, TTK Healthcare Limited, Chennai
11.	Dr. Minakshi Rohilla, PGIMER, Chandigarh
12.	Mr S B Mishra, MHL Healthcare Limited, Muzaffarnagar
13.	Mr Girish R Shah, SMB Corporation of India, Mumbai
14.	Mr Anupam Rai, SMB Corporation of India, Mumbai
15.	Mr Siby Varghese, Rubber Research Institute of India, Rubber Board, Kottayam

9.2.3 The nomination of above members as 'Expert' to ISO Working Groups has been considered by BIS based on the recommendations of the Sectional Committee taking into account that he/she would actively participate in the projects concerned. By accepting an appointment as an Expert, the respective members are committing to actively participate in the Working Group to which he/she is appointed and to fulfill the obligations associated with participation. The Working Group Experts are also required to inform the National Mirror Committee (i.e the concerned BIS Technical Committee that has the liaison with the ISO Technical Committee) of their contribution and progress of the work. The level of contribution of the nominated Working Group Experts may be reviewed and decision may be taken regarding continuation/ termination of nomination.

The Committee may kindly consider.

9.3 Identification of Working Group Experts in ISO Technical Committees

The Organizations / Members may propose for nomination of experts in the WGs considering the following:

- a. The knowledge and expertise of the expert in the subject area.
- b. The willingness of the member to fulfill the responsibilities and expectations and commitment to devote ample time for international standardization activities.

The Committee may kindly consider.

9.4 Harmonization of Indian Standards with International Standards

9.4.1 ISO comprising of global experts on various subjects regularly bring out International Standards. The Sectional Committees on a regular basis needs to review the ISO Standards published against the existing National Standards, current trade practices, consumer expectations, global trends, etc and decide for review of the published National Standards. In the process, Sectional Committees after a close scrutiny of the ISO Standards, may decide on adoption/adaptation of the ISO Standards keeping in view the technical relevance of the subject to the national conditions. Harmonization is not undertaken in case the ISO Standards are not relevant to Indian conditions or would put the Indian industry at disadvantage. The Sectional Committees while reviewing such ISO Standards also explore the possibility of adopting such ISO Standards on which no Indian Standards exist.

9.4.2 The list of Standards published by ISO/ TC 157 along with their status of adoption is given at [Annexure-C \(Page 16-17\)](#).

The Committee may kindly note.

9.5 Summary of ballots

9.5.1 The Summary of ballots closed during Q1 are given below:

Type	Ballot Reference	Ballot title	Ballot start date	Ballot end date	Vote casted
CIB	ISO 19671:2018	Additional lubricants for male natural rubber latex condoms — Effect on condom strength	2024-01-15	2024-06-03	Revise/Amend

The Committee may kindly note.

9.5.2 The ballots received from ISO/TC 157 Secretariat and are open during Q2/Q3 are:

Type	Committee / Working Group	Reference	Start date	End date
CIB	ISO/TC 157	Reappointment of Dr. K. Sivakumar as the WG 17 Convenor	2024-07-10	2024-08-09
DIS	ISO/TC 157	ISO/DIS 4074 (Ed 4) Natural rubber latex male condoms — Requirements and test methods	2024-07-23	2024-10-15

The Committee may kindly deliberate and decide further course of action.

ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Obstetric and Gynaecological Instruments and Appliances Sectional Committee (MHD 03) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

10.2 The progress of development of Indian Standards at various stages is given below:

Stage	No. of Documents
Under Print	2
Under Development	20

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 All Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archiving in the light of technological developments that have happened so far in relation to these standards. This exercise has to be completed in a time bound manner. The details in this regard are given below:

Total as per PoW	Under Development	Under Print	Remaining	Under Progress (out of the remaining)	Pending
50	20	1	29	0	29

11.1.2 The list of the above Indian Standards at various stages is given at [Annexure-D \(Page 18-19\)](#).

The Committee may kindly review.

11.2 Review of Standards as per 5-year cycle

11.2.1 As per the policy of BIS, the Indian Standards which have completed five years since their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for

their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

11.2.2 With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document in respect of each of the Indian Standards which are due for revision.

11.2.3 There are currently no Indian Standards due for review in Quarter-2

The Committee may kindly note.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

12.1 The issues arising out of previous meetings are discussed in the corresponding agenda items.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 03 is scheduled on 06th December 2024.

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

ANNEXURE-A**(Item 2.2)*****Composition of Sectional Committee***

S.No.	Organization	Member Name	Role	Attendance
1.	In Individual Capacity	Dr. Suneeta Mittal	Chairperson	2/2
2.	Association of Indian Medical Device Industry, New Delhi	Mr. C.S Prasad	Alternate Member	2/2
3.	Association of Indian Medical Device Industry, New Delhi	Mr. Ankur Bhargava	Alternate Member	
4.	Association of Indian Medical Device Industry, New Delhi	Mr. Pradeep Narkhede	Principal Member	
5.	Association of Indian Medical Device Industry, New Delhi	Mr. Sumedh Kaulgud	Alternate Member	
6.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu	Principal Member	
7.	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan	Alternate Member	
8.	Central Drugs Standard Control Organization, New Delhi	Mr. Aniruddh Singh Negi	Alternate Member	
9.	Central Drugs Testing Laboratory, Mumbai	Dr C Hariharan	Principal Member	2/2
10.	Central Drugs Testing Laboratory, Mumbai	Ms Sukhada Ajay Navratne	Alternate Member	
11.	Central Drugs Testing Laboratory, Mumbai	Mr. Amol Akash	Alternate Member	
12.	Chemco Plastic Industries Private Limited, Mumbai	Ms. Rupande Sampat	Alternate Member	
13.	Chemco Plastic Industries Private Limited, Mumbai	Mr. Gaurav Saraogi	Principal Member	
14.	Corporate Channel India Private Limited, Mumbai	Mr. Vinod Kumat	Principal Member	2/2
15.	Corporate Channel India Private Limited, Mumbai	Mr. Ramnick Dagarria	Alternate Member	
16.	HLL Lifecare Limited, Thiruvananthapuram	Mr. R Mukund	Alternate Member	2/2
17.	HLL Lifecare Limited, Thiruvananthapuram	Ms. Smitha L. G	Principal Member	
18.	HLL Lifecare Limited, Thiruvananthapuram	Mr. Manikandan S A	Alternate Member	
19.	Indian Institute of Technology, Kharagpur	Dr S. K. Guha	Principal Member	1/2
20.	Indus Medicare Limited, Hyderabad	Mr. P. J. Reddy	Principal Member	2/2
21.	Indus Medicare Limited, Hyderabad	Dr. Biswaranjan Mohanthy	Alternate Member	
22.	Johnson and Johnson Private Limited, Mumbai	Mr. Hemant Sonawane	Principal Member	2/2

23.	Johnson and Johnson Private Limited, Mumbai	Mr. Bhuwandeep Singhla	Alternate Member	
24.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Arjun Thimmaiah	Principal Member	2/2
25.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Satyan Sharma	Alternate Member	
26.	Kalam Institute of Health Technology, Vishakhapatnam	Mr. Mohan Ragul	Alternate Member	
27.	MHL Healthcare Limited, Muzaffarnagar	Dr. Puneet Manocha	Principal Member	2/2
28.	MHL Healthcare Limited, Muzaffarnagar	Mr. Sudhansu Bhusan Mishra	Alternate Member	
29.	Office of Development Commissioner (MSME), New Delhi	Dr. Suvankar Santra	Principal Member	2/2
30.	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr G.R.V. Prasad (Nomination to be updated)	Principal Member	1/2
31.	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Minakshi Rohilla	Alternate Member	
32.	Pregna International Limited, Pune	Mr. Ajit Raje	Principal Member	2/2
33.	Pregna International Limited, Pune	Mr. Ranjit Gaikwad	Alternate Member	
34.	Rubber Research Institute of India, Rubber Board, Kottayam	Dr. Shera Mathew	Alternate Member	1/2
35.	Rubber Research Institute of India, Rubber Board, Kottayam	Dr. Siby Varghese	Principal Member	
36.	SMB Corporation of India, Mumbai	Mr. Anupam Rai	Alternate Member	2/2
37.	SMB Corporation of India, Mumbai	Mr. Girish R. Shah	Principal Member	
38.	TTK Healthcare Limited, Chennai	Mr. Brij Balaji Singh	Principal Member	2/2
39.	TTK Healthcare Limited, Chennai	Mr. John Selwyn Daniel	Alternate Member	
40.	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Bindu Bajaj	Principal Member	1/2
41.	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Jyotsna Suri	Alternate Member	
42.	In Personal Capacity	Dr. K. Sivakumar	Personal Capacity	2/2
43.	In Personal Capacity	Dr. Malabika Roy	Personal Capacity	2/2
44.	In Personal Capacity	Dr. Amit Sen Gupta	Personal Capacity	2/2

ANNEXURE-B

(Item 3.3)

Comments received on WC Drafts

S. No.	Doc No.	Title	Commentator	Organization	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings
1.	MHD 3 (25271)	Sims Pattern Double-Ended Sharp Uterine Curette Specification (<i>first revision</i>)	Minakshi Rohilla	PGIMER, Chandigarh	<p>Clause 4</p> <p>There is no need of sharp ends on both sides. we always need one sharp and one blunt end for the curettage.</p> <p>Clause 5.3</p> <p>surface should not be polished bright. It should be matte finish for better surgical use and to avoid glare.</p>	<p>Clause 4</p> <p>There is no need of sharp ends on both sides. we always need one sharp and one blunt end for the curettage.</p> <p>Clause 5.3</p> <p>surface should not be polished bright. It should be matte finish for better surgical use and to avoid glare.</p>
2.	MHD 3 (25272)	Cannula Intra-Uterine Hysterosalpingography Specification (<i>first revision</i>)	Minakshi Rohilla	PGIMER, Chandigarh	<p>Clause 1</p> <p>Adjustable rubber stopper should not be denatured easily with high temperature</p> <p>Clause 2</p> <p>Attachment for fixing vulsellum forceps will be helpful surgically and good idea to have it.</p>	<p>Clause 1</p> <p>Adjustable rubber stopper should not be denatured easily with high temperature</p> <p>Clause 2</p> <p>Attachment for fixing vulsellum forceps will be helpful surgically and good idea to have it.</p>
3.	MHD 3(25274)	MTP Suction Apparatus Specification Part 1 Manually Operated (<i>third revision</i>)	Minakshi Rohilla	PGIMER, Chandigarh	<p>Clause 3</p> <p>Do we have real need of stainless-steel Cannula now. Everywhere we are using plastic karman canula now. karman canulas are much handy and light in weight.</p>	<p>Clause 3</p> <p>Do we have real need of stainless-steel Cannula now. Everywhere we are using plastic karman canula now. karman canulas are much handy and light in weight.</p>
4.	MHD 3(25275)	MTP Suction Apparatus Specification Part 2 Electrical-Cum-Manually Operated (<i>second revision</i>)	Minakshi Rohilla	PGIMER, Chandigarh	<p>Clause 8.1</p> <p>There is no need of stainless steel canula and should not be polished bright if it is essential at some part of the country.</p> <p>Clause 4.1</p>	<p>Clause 8.1</p> <p>I think there is no need of stainless steel canula and should not be polished bright if it is essential at some part of the country.</p> <p>Clause 4.1</p>

					There should be proper alignment between canula and tubing connecting to suction machine. there should not be any need of connecting holder in between canula and tubing it releases vaccum created. Standard aligned sizes of canula and tubing should be available. thanks.	There should be proper alignment between canula and tubing connecting to suction machine. there should not be any need of connecting holder in between canula and tubing it releases vaccum created. Standard aligned sizes of canula and tubing should be available.
5.	MHD 3(25275)	MTP Suction Apparatus Specification Part 2 Electrical-Cum-Manually Operated (<i>second revision</i>)	Mr. Asok Kumar Raghavan Nair	Abbott Healthcare India Private Limited, Mumbai	Clause 4 The electrically operated MTP apparatus should conform to the general requirement of electromechanical safety ISO 60601 or its IS equivalent	Clause 4 Committee to deliberate on the requirements to be incorporated and include it in the standard.
6.	MHD 3(26025)	Sims Pattern Double-ended Vaginal Speculum Specification (<i>first revision</i>) of IS 6112	Mr. Asok Kumar Raghavan Nair	Abbott Healthcare India Private Limited, Mumbai	Clause 3 There should not be any mention of a specific matel as this will stifle innovation. The only fucntional requirement to resist a force of 50 N only should be specified as well as the fact that it should conform to Biocompatability requirement as per ISO 10993 series.	Clause 3 The Vaginal speculum shall be of any biocompatible material conforming to the requirements as specified in 10993.
7.	MHD 03(26025)	Sims Pattern Double-ended Vaginal Speculum Specification (<i>first revision</i>) of IS 6112	Dr. Amit Sen Gupta	In Personal Capacity	Clause 3 Safe biocompatible bio-materials of light weight – medical grade plastics disposable is available. Secondly: weight specification should also be mentioned.	
8.	MHD 03(26029)	Suction Type Endometrial Biopsy Curette – Specification (<i>first revision</i> of IS 6510)	Dr. Amit Sen Gupta	In Personal Capacity	Clause 7 Instruction for use to be added. Clause 3 Endometrial biopsy curette - Disposable Pipelle (with or without syringe) made of plastic and medicated PVC medical grade is available and very safe and light weight and	

					comfortable;	
9.	MHD 3(26031)	Obstetrics Instruments Forceps Ovum Shape and Dimensions (<i>second revision</i>) of IS 6578	MS. SMITHA L. G	HLL Lifecare Limited	Clause 4 Preferable Grade of stainless steel can be include	Clause 4 Grade of Stainless steel preferred:SS 316
10.	MHD 03 (26033)	Gynaecological Instruments Forceps Uterine Dressing Bozemanns Pattern Shape and Dimensions	Dr. Amit Sen Gupta	In Personal Capacity	Clause 3 Straight and curved shape is available, this document possibly showed only straight.	

ANNEXURE-C

(Item 9.4.2)

List of ISO Standards Published by ISO/TC 157 Secretariat

ISO/TC 157		MHD-03		
Published standards	19	Adopted	Under Development	Not adopted
Under Development	2	17	2	-

Sr. no	ISO	Title	Existing IS	Status of adoption
1	ISO 4074:2015	Natural rubber latex male condoms — requirements and test methods	IS/ISO 4074: 2015	Adopted
2	ISO 7439:2023	Copper-bearing contraceptive intrauterine devices — Requirements and tests	MHD/03/23554	Under print
3	ISO 8009:2014	Mechanical contraceptives — Reusable natural and silicone rubber contraceptive diaphragms — Requirements and tests	IS/ISO 8009: 2014	Adopted
4	ISO 11249:2018	Copper-bearing intrauterine contraceptive devices — Guidance on the design, execution, analysis and interpretation of clinical studies	IS/ISO 11249: 2018	Adopted
5	ISO 16037:2002	Rubber condoms for clinical trials — Measurement of physical properties	IS/ISO 16037: 2002	Adopted
6	ISO 16037: 2002/ AMD 1:2011	Rubber condoms for clinical trials — Measurement of physical properties — Amendment 1	AMD 1 to IS/ISO 16037: 2002	Adopted
7	ISO 16038:2017	Male condoms — Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms	IS 17692: 2021	Adopted
8	ISO 19351:2019	Fallopian rings — Requirements and test methods	IS 13009: 2021	Adopted
9	ISO 19671:2018	Additional lubricants for male natural rubber latex condoms — Effect on condom strength	IS 17810: 2022	Adopted
10	ISO/TR 19969:2018	Guidance on sample handling for determination of bursting volume and pressure, and testing for freedom from holes for male condom	IS 17811: 2022	Adopted
11	ISO 23409: 2011	Male condoms — Requirements and test methods for condoms made from synthetic materials	IS/ISO 23409: 2011	Adopted
12	ISO/TR 24484:2023	Female condoms — Use of ISO 25841 and the quality management of female	MHD/03/23553	Adopted

		condoms		
13	ISO 25841:2017	Female condoms — Requirements and test methods	IS 17962: 2022	Adopted
14	ISO 25841: 2017/ AMD 1:2020	Female condoms — Requirements and test methods — Amendment 1	IS 17962: 2022	Adopted
15	ISO 29941:2010	Condoms — Determination of nitrosamines migrating from natural rubber latex condoms	IS/ISO 29941: 2010	Adopted
16	ISO 29942:2011	Prophylactic dams — Requirements and test methods	IS/ISO 29942: 2011	Adopted
17	ISO 29943-1:2017	Condoms — Guidance on clinical studies — Part 1: Male condoms, clinical function studies based on self-reports	IS/ISO 29943 (Part 1): 2017	Adopted
18	ISO 29943-2:2017	Condoms — Guidance on clinical studies — Part 2: Female condoms, clinical function studies based on self-reports	IS/ISO 29943 (Part 2): 2017	Adopted
19	ISO /TS 23148:2024	Compatibility of lubricants with synthetic male condoms		Under Development

ANNEXURE-D**(Item 11.1.2)*****List of Indian Standards (pre-2000)***

Sr. No.	IS No.	Title	Remarks
1	IS 5829: 1982	Specification for sound uterine (First Revision)	MHD/03/25156
2	IS 5849: 1970	Retractor Anterior Vaginal Wall Sim's pattern	MHD/03/25157
3	IS 5906: 1970	Speculum Vaginal Cusco's pattern	MHD/03/25158
4	IS 6111: 1971	Specification for curette uterine Suction Type	MHD/03/25159
5	IS 6112: 1971	Speculum Vaginal Double Ended Sim's Pattern	MHD/03/26025
6	IS 6114: 1991	Gynaecological instruments forceps uterine vulsellum - Shape and dimensions (First Revision)	MHD/03/26026
7	IS 6115: 1991	Gynaecological instruments – Forceps uterine tenaculum – Shape and dimensions (First Revision)	MHD/03/26027
8	IS 6373: 1971	Specification for sucker mucus	MHD/03/25160
9	IS 6499: 1971	Curette Uterine Double-ended Sharp Sim's Pattern	MHD/03/25271
10	IS 6505: 1971	Curette Uterine Double-ended Sharp and Blunt Sim's Pattern	MHD/03/26028
11	IS 6510: 1971	Specification for curette endometrial biopsy suction type	MHD/03/26029
12	IS 6565: 1972	Stethoscope foetoscope for Foetal Heart Sounds Pinard's Pattern	MHD/03/26030
13	IS 6578: 1992	Obstetrics instruments – Forceps ovum – Shape and dimensions (First Revision)	MHD/03/26031
14	IS 6584: 1972	Dilators Uterine Single Ended Hegar s Pattern	MHD/03/26032
15	IS 6589: 1992	Gynaecological Instruments - Forceps uterine dressing Bozemann s pattern - Shape and dimensions	MHD/03/26033
16	IS 6957: 1973	Specification for curette blunt uterine	MHD/03/26034
17	IS 6958: 1973	Specification for knife decapitation	Withdrawn
18	IS 6959: 1973	Specification for scissors embryotomy curved on flat	
19	IS 6960: 1973	Specification for catheters metal female	
20	IS 6999: 1973	Specification for Cannula Artificial Insemination	
21	IS 7080 (Part 1): 1992	MTP suction apparatus – Specification Part 1 manually operated Second Revision	MHD/03/25274
22	IS 7080 (Part 2): 1992	MTP suction apparatus – Specification Part 2 electrical and manually operated First Revision	MHD/03/25275
23	IS 7080 (Part 3): 1992	MTP suction apparatus specification Part 3 electrically operated	Under print MHD/03/20943
24	IS 7100: 1973	Hook Decapitation Jardine's Pattern	
25	IS 7103: 1973	Specification for scissors episiotomy	
26	IS 7115: 1973	Specification for apparatus tubal patency	
27	IS 7116: 1973	Specification for forceps midwifery short	
28	IS 7117: 1973	Specification for scissors umbilical cord	

29	IS 7432: 1974	Clamp Myomectomy Bonney's Pattern	
30	IS 7433: 1992	Obstetrics Instruments – Forceps round ligament Bonney's pattern – Shape and dimensions	
31	IS 7475: 1992	Obstetric instruments – Clamp vaginal angled – Shape and dimensions (First Revision)	
32	IS 7480: 1974	Perforator Simpson's Pattern	
33	IS 7484: 1974	Retractor Vaginal Purandare's Pattern	
34	IS 7725: 1975	Hook IUCD Shirodkar's Pattern	
35	IS 7735: 1992	Forceps sponge holding – Shape and dimensions (First Revision)	
36	IS 7736: 1975	Specification for screw myoma	
37	IS 7737: 1975	Specification for forceps punch cervical biopsy	
38	IS 7964: 1992	Obstetric instruments – Forceps caesarean section haemostasis green – Armytage pattern – Shape and dimensions (First Revision)	
39	IS 7981 (Part 1): 1976	Instruments Tuboplasty – Part I Occluder Cervical Shirodkar's Pattern	
40	IS 7981 (Part 2): 1976	Specification For Instruments Tuboplasty – Part II Cannula Shirodkar's Pattern	
41	IS 7981 (Part 3): 1976	Instruments Tuboplasty – Part III Guide Shirodkar's Pattern	
42	IS 7981 (Part 4): 1976	Instruments Tuboplasty – Part IV Probe Single Ended Shirodkar's Pattern	
43	IS 7981 (Part 5): 1976	Instruments Tuboplasty – Part V Probe Double-Ended Shirodkar's Pattern	
44	IS 8313: 1977	Specification for cannula flexible karman type	
45	IS 8314: 1977	Forceps Midwifery Modified Kedarnath Das Pattern without Axis Traction	Withdrawn
46	IS 8342: 1977	Forceps Midwifery Modified Kedarnath Das Pattern with Axis Traction	Withdrawn
47	IS 8458: 1977	Manipulators Uterine Dr Purandare's Pattern	Withdrawn
48	IS 8459: 1977	Specification for menstrual regulation syringe	
49	IS 9756: 1981	Specification for cups vacuum extraction	Subject taken up for R&D
50	IS 10156: 1982	Specification for cannula intra-uterine hysterosalpingography	MHD/03/25272
51	IS 10545: 1992	Gynaecological and obstetric instruments - Clamp curved on flat Heaney s pattern - Shape and dimensions	
52	IS 12256: 1988	Specification for curette uterine biopsy angled	
53	IS 12270: 1988	Cannula Spackmann's Pattern	
54	IS 12271: 1988	Specification for laproscopic trocar and cannula	MHD/03/25273