

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
Bureau of Indian Standards

AGENDA

**19TH MEETING OF OBSTETRIC AND GYNAECOLOGICAL INSTRUMENTS AND
APPLIANCES SECTIONAL COMMITTEE, MHD 03**

Date: 11-08-2023	Time: 14:00h
Venue: Online (BIS WebEx Platform)	
Meeting No: 2516 933 4703	Password: Mhd3@19
Link:	
https://bismanak.webex.com/bismanak/j.php?MTID=m24c665169da5b5d8069d8957b90e02af	
Chairman:	Member Secretary:
Dr Suneeta Mittal (In-Personal capacity)	Ms Gurpreet Kaur (Scientist-B)

ITEM 0 WELCOME AND OPENING REMARKS

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The minutes of the last (18th) meeting were circulated to all the members after approval of the Chairperson vide email dated 22.02.2023. No comments have been received.

The Committee may formally confirm the minutes.

ITEM 2 PROCESS REFORMS IN STANDARDIZATION

2.1 BIS has instituted several process reforms in respect of formulation of Indian Standards. The process reforms introduced in the Standardization activities have been outlined in **Annex-A**.

2.2 Annual Meeting Calendar

As per guidelines, every Sectional Committee is required to meet once per quarter. In this regard, each committee needs to approve the annual meeting calendar in the beginning of the year. The annual calendar for MHD-02 is mentioned below.

Quarter	Q1	Q2	Q3	Q4
Date	11 th Aug, 2023 (Friday)	6th Oct, 2023 (Friday)	8th Dec, 2023 (Friday)	1 st Mar, 2024 (Friday)

The Committee may kindly note.

ITEM 3 SCOPE AND COMPOSITION OF COMMITTEE

3.1 Scope

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

The Committee may kindly examine the scope.

3.2 Composition

The present composition of MHD03 is given in [Annex-B](#) (Page 4-5). The Committee may review the composition according to following BIS guidelines:

- a. Consumer interests shall, as far as possible, predominate. In case, non-industry interests are less than two third, it may be reviewed to ensure that 2/3rd of the total representation on the committee is from non-industry.
- b. Only relevant organizations/government departments/consumer organizations and regulatory bodies that are related to the subject may be offered representation.
- c. Non-active members to be withdrawn (Attendance in the last three meetings may be considered for reviewing the representation).
- d. Young professionals who can contribute in the working of the committee may be co-opted. The committee may deliberate on the same and advice.

The Committee may please note.

3.3 Members are also requested to provide their latest details like E-mail, Phone No, enabling secretariat to make correspondence and send documents/Agenda/Minutes etc. through e-mail.

3.4 Co-option request has been received from (details in **Annex-C**):

- Dr Puneet Manocha, Managing Director, MHL Healthcare Limited
- Mr Gaurav Saraogi, Managing Director, Chemco Plastic Industries Pvt. Ltd.

The Committee may kindly deliberate.

ITEM 4 DRAFT STANDARDS FOR FINALIZATION

Sr No.	Doc No.	Title	Comments
1	20943	MTP Suction Apparatus – Specification Part 3 Electrically Operated (Third Revision)	Dr Minakshi Rohilla: Regarding workmanship and finish of the steel cannula, it is best to avoid bright polish as it might cause glare of light in the operation theatre (9.1.3).
2	21403	NSV Instruments – Specification	No comments received
3	21503	PPIUCD Insertion Forceps – Specification	Dr Minakshi Rohilla: The overall weight of PPIUCD Forceps to be reduced as it is bulky and heavy when used in comparison to other instruments.

The Committee may kindly deliberate.

ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

ISO standards to be considered for adoption are further given in **Item 7.1.** (Annex-D)

The Committee may please note.

ITEM 6 DRAFTS UNDER PREPARATION

6.1 The following drafts are to be included with comments received from experts:

Sr No.	Document No.	Title	Doc Type
1	19202	Menstrual Cups – Specification	New
2	20629	Intrauterine Contraceptive Devices – Copper-T (380A) – Specification	New

6.2 The following documents to be referred to panels for further inputs:

- a. Vaginal Ring
- b. LNG IUD

The Committee may please note. The deliberations on 6.1 and 6.2 to be taken up in detail in the meetings of Q2 and Q3.

ITEM 7 INTERNATIONAL ACTIVITIES

7.1 India is a P-member of ISO/TC 157 ‘Non-systemic contraceptives and STI barrier prophylactics. A list of ISO Standards published by ISO/TC 157 is given in [Annex-D](#) (Page 6 -7). Present status of adoption of such ISO Standards has been provided.

7.2 The Plenary and WG meetings of ISO/TC 157 was held in Edinburgh, UK from 22nd to 25th May 2023.

The approved resolutions of the meeting are given at **Annex-E**.

ITEM 8 REVIEW OF STANDARDS & PROGRAMME OF WORK

8.1 The list of standards in MHD-03 that published before the year 2000 is given in [Annex-F](#) (Page 8-9).

8.2 The programme of work is available at e-BIS Portal:

https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/pow_details

The Committee may please note.

ITEM 9 DATE AND PLACE OF NEXT MEETING

ITEM 10 ANY OTHER BUSINESS

ANNEX-B
(Item 3.2)
Composition

SI No.	Name of Organization	Represented by
1.	In Personal Capacity	Dr. Suneeta Mittal (Chairperson)
2.	All India Institute of Medical Sciences, New Delhi	Dr. Sunesh Kumar Dr. J.B. Sharma (Alternate)
3.	Central Drugs Standard Control Organization, New Delhi	Dr. Ravi Kant Sharma (Alternate)
4.	Central Drug Testing Laboratory Mumbai	Dr. Raman Mohan Singh Smt. Sayali Umesh Warde (Alternate)
5.	Central Drug Testing Laboratory, Chennai	Smt. C. Vijaya Lakshmi Smt. J. Uma Maheswari (Alternate)
6.	Central Institute of Petrochemicals Engineering & Technology (CIPET)	Dr K. P. Bhuvana Dr. Manoranjan Biswal Dr. Nalini R
7.	Corporate Channel India Pvt. Ltd., Udaipur	Shri Vinod Kumat Shri Ramnick Dagaria (Alternate)
8.	Council of Scientific & Industrial Research, New Delhi	Shri Dhirendra Bansal Smt. Shashi Moitra (Alternate)
9.	Directorate General of Armed Forces Medical Services, New Delhi	Brig. Surender Mohan Col. Pankaj Talwar (Alternate)
10.	Directorate General of Health Services, New Delhi	Dr. Sudha Prasad
11.	Employees State Insurances Corporation Ltd., New Delhi	Dr. Sangeeta Gupta Dr. Sunita Jindal (Alternate)
12.	Family Planning Association of India, New Delhi	Dr. (Mrs) Suchitra Wadhwa Shri Sreedharan Nair (Alternate)
13.	Federation of Obst & Gynae Society of India, Mumbai	Dr. (Prof.) Alka Kriplani Dr. Hrishikesh D. Pai (Alternate)
14.	TTK Healthcare Limited (Protective Devices Division), Chennai	Shri Brij Balaji Singh Shri R. Saranyan (Alternate)
15.	Hindustan Latex Family Planning Promotion Trust, Noida	Dr. Abha Jha Dr. Pankhuri Rai (Alternate)
16.	HLL Lifecare Limited, Thiruvanthapuram	Ms. Smitha L. G Mr. Mukund. R (Alternate)
17.	In Personal Capacity	Dr. Gulshan Jit Singh
18.	In Personal Capacity	Dr. Malabika Roy
19.	In Person Capacity	Dr. K. Sivakumar
20.	In Person Capacity	Dr. Amit Sen Gupta
21.	In Person Capacity	Dr. N. Murugesan
22.	Indian Medtronic Pvt. Ltd, Gurugram	Ms. Latika Vats Shri. Sanjeev Minhas (Alternate)
23.	Indian Council of Medical Research New Delhi	Dr. R.S. Sharma Dr. Shalini Singh (Alternate)
24.	Indian Institute of Technology, Delhi	Dr. (Prof.) Naresh Bhatnagar

25.	Indian Institute of Technology, Kanpur	Dr. (Prof.) Asima Pradhan
26.	Indian Institute of Technology, Kharagpur	Dr. (Prof.) S.K.Guha
27.	Indus Medicare Ltd., Hyderabad	Shri P.J. Reddy Shri. Biswaranjan Mohanthy (Alternate)
28.	Johnson & Johnson Pvt. Ltd., Gurgaon	Shri Yateen Shah Ms. Aishwarya Nair (Alternate 2)
29.	Kalam Institute of Health Technology, Vishakhapatnam	Dr. Jitendar Sharma Shri Dilip Kumar Chekuri (Alternate)
30.	Maulana Azad Medical College, New Delhi	Dr. Y. M. Mala Dr. Latika Sahu (Alternate)
31.	Ministry of Health & Family Welfare New Delhi	Dr. S.K.Sikdar Dr. Teja Ram (Alternate)
32.	National Institute for Research in Reproductive Health, ICMR, Mumbai	Dr. Beena Joshi Dr. Rahul Gajbhiye (Alternate)
33.	Office of Development Commissioner, Small Scale Industries, New Delhi	Shri Dharmendra Prakash Mrs. Asha Kak (Alternate)
34.	Postgraduate Institute of Medical Education & Research Chandigarh	Prof. G.R.V. Prasad Prof. Minakshi Rohilla (Alternate)
35.	Pregna International Ltd., Pune	Shri Ajit Raje Shri Ranjit Gaikwad (Alternate)
36.	Rubber Research Institute of India, Rubber Board, Kottayam	Dr. Siby Varghese Dr. Shra Mathew (Alternate)
37.	Safdurjung Hospital, New Delhi	Dr. Mridula Pawar Dr. Sunil Kumar (Alternate)
38.	SGS Life Sciences Services Chennai	Shri K. Suresh Kumar Danadurai Shri J. Arun (Alternate)
39.	Shriram Institute for Industrial Research, New Delhi	Dr. Binu Bhat Smt. Kamini Kalra (Alternate)
40.	SMB Corporation of India Mumbai	Sh. Girish R Shah Sh. Anupam Rai (Alternate)
41.	Stryker India, Gurgaon	Sh. Shivkumar Hurdale

ANNEX-D

(Item 7.1)

List of ISO Standards Published by ISO/TC 157 Secretariat

ISO/TC 157		MHD-03		
Published standards	18	Adopted	Under Development	Not adopted
Under Development	2	15	-	3

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 7439:2015	Copper-bearing contraceptive intrauterine devices — Requirements and tests	IS/ISO 7439 : 2015	Adopted
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	-	Not 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 condoms	-	Not Adopted
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

ANNEX-F

(Item 8.1)

List of standards published prior to 2000

Sr. No.	IS No.	Title	Remarks
1	IS 5829: 1982	Specification for sound uterine (First Revision)	
2	IS 5849: 1970	Retractor Anterior Vaginal Wall Sim's pattern	
3	IS 5906: 1970	Speculum Vaginal Cusco's pattern	
4	IS 6111: 1971	Specification for curette uterine Suction Type	
5	IS 6112: 1971	Speculum Vaginal Double Ended Sim's Pattern	
6	IS 6114: 1991	Gynaecological instruments forceps uterine vulsellum - Shape and dimensions (First Revision)	
7	IS 6115: 1991	Gynaecological instruments – Forceps uterine tenaculum – Shape and dimensions (First Revision)	
8	IS 6373: 1971	Specification for sucker mucus	
9	IS 6499: 1971	Curette Uterine Double-ended Sharp Sim's Pattern	
10	IS 6505: 1971	Curette Uterine Double-ended Sharp and Blunt Sim's Pattern	
11	IS 6510: 1971	Specification for curette endometrial biopsy suction type	
12	IS 6565: 1972	Stethoscope foetoscope for Foetal Heart Sounds Pinard's Pattern	
13	IS 6578: 1992	Obstetrics instruments – Forceps ovum – Shape and dimensions (First Revision)	
14	IS 6584: 1972	Dilators Uterine Single Ended Hegar s Pattern	
15	IS 6589: 1992	Gynaecological Instruments - Forceps uterine dressing Bozemann s pattern - Shape and dimensions	
16	IS 6957: 1973	Specification for curette blunt uterine	
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	
22	IS 7080 (Part 2): 1992	MTP suction apparatus – Specification Part 2 electrical and manually operated First Revision	
23	IS 7080 (Part 3): 1992	MTP suction apparatus specification Part 3 electrically operated	Doc No. 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	
50	IS 10156: 1982	Specification for cannula intra-uterine hysterosalpingography	
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	