

BUREAU OF INDIAN STANDARDS

Program of Work

MHD 3 : Obstetric and Gynaecological Instruments and Appliances

Scope: To formulate Indian Standards for instruments, appliances and medical devices, used in obstetrics and gynaecology and for contraception; .

Liaison: **ISO TC-157 (P):** *Non-systemic contraceptives and STI barrier prophylactics*

Published Standards

S.No	IS No.	TITLE	Reaffirm M-Y	No. of Amds	Eqv.
1	IS 10156 : 1982 <i>Reviewed In : 2020</i>	Specification for cannula, intra - Uterine, hysterosalpingography	January, 2020	-	Indigenous
2	IS 10545 : 1992 <i>Reviewed In : 2022</i>	Gynaecological and obstetric instruments - Clamp, curved on flat, Heaney's pattern - Shape and dimensions	July, 2022	-	Indigenous
3	IS/ISO 11249 : 2018 ISO 11249 : 2018 <i>ISO 11249:2018</i>	Copper-Bearing Intrauterine Contraceptive Devices “ Guidance on the Design, Execution, Analysis and Interpretation of Clinical Studies		-	Identical under single numbering
4	IS 12256 : 1988 <i>Reviewed In : 2020</i>	Specification for curette, uterine, biopsy, angled	January, 2020	-	Indigenous
5	IS 12270 : 1988 <i>Reviewed In : 2020</i>	Cannula, Spackmann's Pattern	January, 2020	-	Indigenous
6	IS 12271 : 1988 <i>Reviewed In : 2020</i>	Specification for laproscopic trocar and cannula	January, 2020	-	Indigenous
7	IS 13009 : 2021 ISO 19351:2019 <i>ISO 19351:2019</i>	Fallopian rings — Requirements and test methods		-	Identical under dual numbering
8	IS/ISO 16037 : 2002 <i>Reviewed In : 2020</i>	Rubber condoms for clinical trials - Measurement of physical properties	January, 2020	1	Identical under single numbering
9	IS 17692 : 2021 ISO 16038:2017 <i>ISO 16038:2017</i>	Male condoms Guidance on the use of IS ISO 4074 and IS ISO 23409 in the quality management of condoms		-	Identical under dual numbering
10	IS 17810 : 2022 ISO 19671: 2018	Additional lubricants for male natural rubber latex condoms “ Effect on condom strength		-	
11	IS 17811 : 2022 ISO/TR 19969:2018	Guidance on Sample Handling for Determination of Bursting Volume and Pressure and Testing for Freedom from Holes for Male Condom		-	
12	IS 17962 : 2022 ISO 25841:2017 <i>ISO 25841:2017</i>	Female condoms - Requirements and test methods (First Revision)		-	Identical under dual numbering

13	IS 18561 : 2024	No-Scalpel Vasectomy Instruments i ₁ /2 Specification		-	Indigenous
14	IS 18562 : 2024	PPIUCD Insertion Forceps Specification		-	Indigenous
15	IS 18587 : 2024 ISO/TR 24484: 2023 ISO/TR 24484: 2023	Female condoms Use of ISO 25841 and the quality management of female condoms		-	Identical under dual numbering
16	IS/ISO 23409 : 2015 ISO 23409 : 2011 Reviewed In : 2020 ISO 23409 : 2011	Male condoms - Requirements and test methods for condoms made from synthetic materials	January, 2020	-	Identical under single numbering
17	IS/ISO 29941 : 2010 ISO 29941 : 2010 Reviewed In : 2020 ISO 29941 : 2010	Condoms - Determination of nitrosamines migrating from natural rubber latex condoms	January, 2020	-	Identical under single numbering
18	IS/ISO 29942 : 2011 ISO 29942 : 2011 Reviewed In : 2020 ISO 29942:2011	Prophylactic dams - Requirements and test methods	January, 2020	-	Identical under dual numbering
19	IS/ISO 29943-1 : 2017 ISO 29943-1:2017 ISO 29943-1:2017	Condoms Guidance on clinical studies Part 1: Male condoms clinical function studies based on self-reports		-	Identical under single numbering
20	IS/ISO 29943-2 : 2017 ISO 29943-2:2017 ISO 29943-2:2017	Condoms Guidance on clinical studies Part 2: Female condoms clinical function studies based on self-reports		-	Identical under single numbering
21	IS/ISO 4074 : 2015 ISO 4075 : 2015 Reviewed In : 2023 ISO 4074 : 2015	Natural rubber latex male condoms - Requirements and test methods (First Revision)	May, 2023	-	Identical under single numbering
22	IS 5829 : 1982 Reviewed In : 2022	Specification for sound, uterine (First Revision)	July, 2022	-	Indigenous
23	IS 5849 : 1970 Reviewed In : 2022	Retractor, Anterior Vaginal Wall (Sim's pattern)	July, 2022	1	Indigenous
24	IS 5906 : 1970 Reviewed In : 2022	Speculum, Vaginal (Cusco's pattern)	July, 2022	1	Indigenous
25	IS 6111 : 1971 Reviewed In : 2022	Specification for curette, uterine (Suction Type)	July, 2022	1	Indigenous
26	IS 6112 : 1971 Reviewed In : 2022	Speculum, Vaginal, Double Ended (Sim's Pattern)	July, 2022	1	Indigenous
27	IS 6114 : 1991 Reviewed In : 2021	Gynaecological instruments forceps, uterine vulsellum - Shape and dimensions (First Revision)	December, 2021	-	Indigenous
28	IS 6115 : 1991 Reviewed In : 2021	Gynaecological instruments - Forceps, uterine tenaculum - Shape and dimensions (First Revision)	December, 2021	1	Indigenous
29	IS 6373 : 1971 Reviewed In : 2022	Specification for sucker, mucus	July, 2022	-	Indigenous
30	IS 6499 : 1971 Reviewed In : 2022	Curette, Uterine, Double-ended, Sharp, Sim's Pattern	July, 2022	1	Indigenous
31	IS 6505 : 1971 Reviewed In : 2022	Curette, Uterine, Double-ended, Sharp and Blunt, Sim's Pattern	July, 2022	1	Indigenous
32	IS 6510 : 1971 Reviewed In : 2022	Specification for curette, endometrial biopsy, suction type	July, 2022	1	Indigenous
33	IS 6565 : 1972 Reviewed In : 2022	Stethoscope (foetoscope) for - Foetal Heart Sounds, Pinard's Pattern	July, 2022	-	Indigenous

34	IS 6578 : 1992 Reviewed In : 2022	Obstetrics instruments - Forceps, ovum - Shape and dimensions (First Revision)	July, 2022	-	Indigenous
35	IS 6584 : 1972 Reviewed In : 2022	Dilators, Uterine, Single Ended, Hegar's Pattern	July, 2022	-	Indigenous
36	IS 6589 : 1992 Reviewed In : 2021	Gynaecological Instruments - Forceps, uterine, dressing, Bozemann's pattern - Shape and dimensions	July, 2021	-	Indigenous
37	IS 6957 : 1973 Reviewed In : 2022	Specification for curette, blunt, uterine	July, 2022	1	Indigenous
38	IS 6959 : 1973 Reviewed In : 2022	Specification for scissors, embryotomy, curved on flat	July, 2022	1	Indigenous
39	IS 6960 : 1973 Reviewed In : 2022	Specification for catheters, metal, female	July, 2022	1	Indigenous
40	IS 6999 : 1973 Reviewed In : 2022	Specification for Cannula, Artificial Insemination	July, 2022	-	Indigenous
41	IS 7080 (Part 1) : 1992 Reviewed In : 2022	MTP suction apparatus - Specification: Part 1 manually operated (Second Revision)	July, 2022	1	Indigenous
42	IS 7080 (Part 2) : 1992 Reviewed In : 2022	MTP suction apparatus - Specification: Part 2 electrical - Cum - Manually operated (First Revision)	July, 2022	1	Indigenous
43	IS 7080 (Part 3) : 1992 Reviewed In : 2022	MTP suction apparatus specification: Part 3 electrically operated (Second Revision)	July, 2022	3	Indigenous
44	IS 7080 (Part 3) : 2024	MTP Suction Apparatus Specification Part 3 Electrically Operated (Third Revision)		-	Indigenous
45	IS 7100 : 1973 Reviewed In : 2022	Hook, Decapitation, Jardine's Pattern	July, 2022	2	Indigenous
46	IS 7103 : 1973 Reviewed In : 2022	Specification for scissors, episiotomy	July, 2022	1	Indigenous
47	IS 7115 : 1973 Reviewed In : 2022	Specification for apparatus, tubal patency	July, 2022	1	Indigenous
48	IS 7116 : 1973 Reviewed In : 2022	Specification for forceps, midwifery, short	July, 2022	1	Indigenous
49	IS 7117 : 1973 Reviewed In : 2022	Specification for scissors, umbilical cord	July, 2022	1	Indigenous
50	IS 7432 : 1974 Reviewed In : 2022	Clamp, Myomectomy, Bonney's Pattern	July, 2022	1	Indigenous
51	IS 7433 : 1992 Reviewed In : 2022	Obstetrics Instruments - Forceps, round ligament, Bonney's pattern - Shape and dimensions	July, 2022	-	Indigenous
52	IS /ISO : 2015 ISO 7439 : 2015 Reviewed In : 2023 ISO 7439: 2023	Copper - Bearing contraceptive intrauterine devices - Requirements and tests (First Revision)	August, 2023	-	Modified/Technically Equivalent
53	IS 18593 : 2024 ISO 7439: 2023	Copper-Bearing Contraceptive Intrauterine Devices - Requirements and Tests (ISO 7439 : 2023, MOD (Second Revision)		-	Modified/Technically Equivalent
54	IS 7475 : 1992 Reviewed In : 2022	Obstetric instruments - Clamp, vaginal, angled - Shape and dimensions (First Revision)	July, 2022	-	Indigenous
55	IS 7480 : 1974 Reviewed In : 2022	Perforator, Simpson's Pattern	July, 2022	1	Indigenous
56	IS 7484 : 1974	Retractor, Vaginal, Purandare's	July, 2022	1	Indigenous

	Reviewed In : 2022	Pattern			
57	IS 7725 : 1975 Reviewed In : 2022	Hook, IUCD, Shirodkar's Pattern	July, 2022	-	Indigenous
58	IS 7735 : 1992 Reviewed In : 2022	Forceps, sponge holding - Shape and dimensions (First Revision)	July, 2022	-	Indigenous
59	IS 7736 : 1975 Reviewed In : 2022	Specification for screw, myoma	July, 2022	-	Indigenous
60	IS 7737 : 1975 Reviewed In : 2022	Specification for forceps, punch, cervical biopsy	July, 2022	-	Indigenous
61	IS 7964 : 1992 Reviewed In : 2022	Obstetric instruments - Forceps, caesarean section, haemostasis, green - Armytage pattern - Shape and dimensions (First Revision)	July, 2022	-	Indigenous
62	IS 7981 (Part 1) : 1976 Reviewed In : 2022	Instruments, Tuboplasty - Part I : Occluder, Cervical, Shirodkar's Pattern	July, 2022	-	Indigenous
63	IS 7981 (Part 2) : 1976 Reviewed In : 2022	Specification For Instruments. Tuboplasty - Part II : Cannula, Shirodkar's Pattern	July, 2022	-	Indigenous
64	IS 7981 (Part 3) : 1976 Reviewed In : 2022	Instruments, Tuboplasty - Part III : Guide, Shirodkar's Pattern	July, 2022	-	Indigenous
65	IS 7981 (Part 4) : 1976 Reviewed In : 2022	Instruments, Tuboplasty - Part IV : Probe, Single Ended, Shirodkar's Pattern	July, 2022	-	Indigenous
66	IS 7981 (Part 5) : 1976 Reviewed In : 2022	Instruments, Tuboplasty - Part V : Probe, Double-Ended, Shirodkar's Pattern	July, 2022	-	Indigenous
67	IS/ISO 8009 : 2014 ISO 8009 : 2014 Reviewed In : 2023 ISO 8009 : 2014	Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests (First Revision)	May, 2023	-	Identical under single numbering
68	IS 8313 : 1977 Reviewed In : 2022	Specification for cannula, flexible, karman type	July, 2022	-	Indigenous
69	IS 8459 : 1977 Reviewed In : 2022	Specification for menstrual regulation syringe	July, 2022	-	Indigenous
70	IS 9756 : 1981 Reviewed In : 2022	Specification for cups, vacuum extraction	July, 2022	-	Indigenous

Standards under Development

Projects Approved

SI. No.	Doc No.	Title
1	MHD 3 (26481)	Intrauterine Contraceptive Devices Copper-T 380A Specification
2	MHD 3 (26482)	LNG IUD - Specification

Preliminary Draft Standards

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Drafts Standards in WC Stage

SI. No.	Doc No.	Title
<i>No Records Found</i>		

Draft Standards Completed WC Stage

SI. No.	Doc No.	Title
1	MHD 3 (25271)	SIMS PATTERN DOUBLE-ENDED SHARP UTERINE CURETTE SPECIFICATION First Revision
2	MHD 3 (25272)	Cannula Intra-Uterine Hysterosalpingography Specification First Revision
3	MHD 3 (25274)	MTP Suction Apparatus Specification Part 1 Manually Operated Third Revision
4	MHD 3 (25275)	MTP Suction Apparatus Specification Part 2 Electrical-Cum-Manually Operated Second Revision
5	MHD 3 (26025)	Sims Pattern Double-ended Vaginal Speculum Specification First Revision of IS 6112
6	MHD 3 (26026)	Gynaecological Instruments Forceps Uterine Vulsellum Shape and Dimensions Second Revision of IS 6114
7	MHD 3 (26027)	Gynaecological Instruments Forceps Uterine Tenaculum Shape and Dimensions Second Revision of IS 6115
8	MHD 3 (26028)	Sims Pattern Double-Ended Sharp and Blunt Uterine Curette Specification First Revision of IS 6505
9	MHD 3 (26029)	Suction Type Endometrial Biopsy Curette Specification First Revision of IS 6510
10	MHD 3 (26030)	Foetoscope For Foetal Heart Sounds Pinards Pattern Specification First Revision of IS 6565
11	MHD 3 (26031)	Obstetrics Instruments Forceps Ovum Shape and Dimensions Second Revision of IS 6578
12	MHD 3 (26032)	Single-ended Hegars Pattern Uterine Dilators Specification First Revision of IS 6584
13	MHD 3 (26033)	Gynaecological Instruments Forceps Uterine Dressing Bozemanns Pattern Shape and Dimensions Second Revision of IS 6589
14	MHD 3 (26034)	Curette Blunt Uterine Specification First Revision of IS 6957
15	MHD 3 (26480)	Reusable Menstrual Cups - Specification

Finalized Draft Indian Standard

SI. No.	Doc No.	Title
1	MHD 3 (25156) Revision of: IS 5829:1982	Uterine Sound - Specification second revision
2	MHD 3 (25158) Revision of: IS 5906:1970	Vaginal Speculum Cuscos Pattern Specification first revision
3	MHD 3 (25159) Revision of: IS 6111:1971	Suction Type Uterine Curette Specification first revision
4	MHD 3 (25160) Revision of: IS 6373:1971	Mucus Sucker Specification First revision
5	MHD 3 (25273) Revision of: IS 12271:1988	Laposcopic Trocar And Cannula Specification First Revision

Finalized Draft Indian Standards under Print

SI. No.	Doc No.	Title
1	MHD 3 (25157) Revision of: IS 5849:1970	Anterior Vaginal Wall Retractor Sims Pattern Specification first revision

Total Published Standards:65 Total Standards Under development:23

Aspect Wise Report

Product : 58
Code of Practices : 5
Methods of Test : 3
Terminology : 0
Dimensions : 0
System Standard : 0
Safety Standard : 0
Others : 0
Service Specification : 0
Process Specification : 0

Annexure-I :List of Indian Standards Withdrawn/Superseded

Sl. No.	IS No. & Year	Title
1	IS 10546 : 1983 Reviewed In : 2005	Forceps Uterus Holding Hysteroleb Dartigue s Pattern
2	IS 12418 (Part 1) : 1987 Reviewed In : 2007	Intra-Uterine Contraceptive Devices - Part 1 General Requirements
3	IS 12418 (Part 2) : 1987 Reviewed In : 2005	Intra-uterine Contraceptive Devices - Part 2 Determination of Breaking Force
4	IS 12418 (Part 3) : 1987 Reviewed In : 2005	Intra-uterine Contraceptive Devices - Part 3 Packaging and Labelling
5	IS 12418 (Part 4) : 2000 Reviewed In : 2010	Intra-Uterine Contraceptive Devices - - Part 4 Copper-T 200 B
6	IS/ISO 16038 : 2005 Reviewed In : 2020	Rubber condoms - Guidance on the use of IS ISO 4074 in the quality management of natural rubber latex condoms
7	IS/ISO 25841 : 2014 ISO 25841 : 2014 ISO 25841 : 2014	Female condoms - Requirements and test methods
8	IS 6958 : 1973 Reviewed In : 2022	Specification for knife decapitation
9	IS 6986 : 1973	Forceps Cranioclast and Cephalotribe Combined
10	IS 8314 : 1977 Reviewed In : 2017	Forceps Midwifery Modified Kedarnath Das Pattern without Axis Traction
11	IS 8342 : 1977 Reviewed In : 2017	Forceps Midwifery Modified Kedarnath Das s Pattern with Axis Traction
12	IS 8458 : 1977 Reviewed In : 2022	Manipulators Uterine Dr Purandare s Pattern

Annexure-II :List of Indian Product Standards

Sl. No.	IS No. & Year	Title
1	IS 10156 : 1982 Reviewed In : 2020	Specification for cannula intra - Uterine hysterosalpingography
2	IS 10545 : 1992 Reviewed In : 2022	Gynaecological and obstetric instruments - Clamp curved on flat Heaney s pattern - Shape and dimensions
3	IS 12256 : 1988 Reviewed In : 2020	Specification for curette uterine biopsy angled
4	IS 12270 : 1988 Reviewed In : 2020	Cannula Spackmann s Pattern
5	IS 12271 : 1988 Reviewed In : 2020	Specification for laproscopic trocar and cannula
6	IS 13009 : 2021 ISO 19351:2019	Fallopian rings Requirements and test methods
7	IS 17962 : 2022 ISO 25841:2017 ISO 29061-4 : 2017	Female condoms - Requirements and test methods First Revision
8	IS 18561 : 2024	No-Scalpel Vasectomy Instruments Specification
9	IS 18562 : 2024	PPIUCD Insertion Forceps Specification
10	IS/ISO 29942 : 2011 ISO 29942 : 2011 Reviewed In : 2020 ISO 29942:2011	Prophylactic dams - Requirements and test methods
		Natural rubber latex male condoms - Requirements and test methods First Revision

11	IS/ISO 4074 : 2015 ISO 4075 : 2015 Reviewed In : 2023 ISO 4074 : 2015	
12	IS 5829 : 1982 Reviewed In : 2022	Specification for sound uterine First Revision
13	IS 5849 : 1970 Reviewed In : 2022	Retractor Anterior Vaginal Wall Sim s pattern
14	IS 5906 : 1970 Reviewed In : 2022	Speculum Vaginal Cusco s pattern
15	IS 6111 : 1971 Reviewed In : 2022	Specification for curette uterine Suction Type
16	IS 6112 : 1971 Reviewed In : 2022	Speculum Vaginal Double Ended Sim s Pattern
17	IS 6114 : 1991 Reviewed In : 2021	Gynaecological instruments forceps uterine vulsellum - Shape and dimensions First Revision
18	IS 6115 : 1991 Reviewed In : 2021	Gynaecological instruments - Forceps uterine tenaculum - Shape and dimensions First Revision
19	IS 6373 : 1971 Reviewed In : 2022	Specification for sucker mucus
20	IS 6499 : 1971 Reviewed In : 2022	Curette Uterine Double-ended Sharp Sim s Pattern
21	IS 6505 : 1971 Reviewed In : 2022	Curette Uterine Double-ended Sharp and Blunt Sim s Pattern
22	IS 6510 : 1971 Reviewed In : 2022	Specification for curette endometrial biopsy suction type
23	IS 6565 : 1972 Reviewed In : 2022	Stethoscope foetoscope for - Foetal Heart Sounds Pinard s Pattern
24	IS 6578 : 1992 Reviewed In : 2022	Obstetrics instruments - Forceps ovum - Shape and dimensions First Revision
25	IS 6584 : 1972 Reviewed In : 2022	Dilators Uterine Single Ended Hegar s Pattern
26	IS 6589 : 1992 Reviewed In : 2021	Gynaecological Instruments - Forceps uterine dressing Bozemann s pattern - Shape and dimensions
27	IS 6957 : 1973 Reviewed In : 2022	Specification for curette blunt uterine
28	IS 6959 : 1973 Reviewed In : 2022	Specification for scissors embryotomy curved on flat
29	IS 6960 : 1973 Reviewed In : 2022	Specification for catheters metal female
30	IS 6999 : 1973 Reviewed In : 2022	Specification for Cannula Artificial Insemination
31	IS 7080 (Part 1) : 1992 Reviewed In : 2022	MTP suction apparatus - Specification Part 1 manually operated Second Revision
32	IS 7080 (Part 2) : 1992 Reviewed In : 2022	MTP suction apparatus - Specification Part 2 electrical - Cum - Manually operated First Revision
33	IS 7080 (Part 3) : 2024	MTP Suction Apparatus Specification Part 3 Electrically Operated Third Revision
34	IS 7100 : 1973 Reviewed In : 2022	Hook Decapitation Jardine s Pattern
35	IS 7103 : 1973 Reviewed In : 2022	Specification for scissors episiotomy
36	IS 7115 : 1973 Reviewed In : 2022	Specification for apparatus tubal patency
37	IS 7116 : 1973 Reviewed In : 2022	Specification for forceps midwifery short
38	IS 7117 : 1973 Reviewed In : 2022	Specification for scissors umbilical cord
39	IS 7432 : 1974	Clamp Myomectomy Bonney s Pattern

	Reviewed In : 2022	
40	IS 7433 : 1992 Reviewed In : 2022	Obstetrics Instruments - Forceps round ligament Bonney s pattern - Shape and dimensions
41	IS 18593 : 2024	Copper-Bearing Contraceptive Intrauterine Devices - Requirements and Tests ISO 7439 2023 MOD Second Revision
42	IS 7475 : 1992 Reviewed In : 2022	Obstetric instruments - Clamp vaginal angled - Shape and dimensions First Revision
43	IS 7480 : 1974 Reviewed In : 2022	Perforator Simpson s Pattern
44	IS 7484 : 1974 Reviewed In : 2022	Retractor Vaginal Purandare s Pattern
45	IS 7725 : 1975 Reviewed In : 2022	Hook IUCD Shirodkar s Pattern
46	IS 7735 : 1992 Reviewed In : 2022	Forceps sponge holding - Shape and dimensions First Revision
47	IS 7736 : 1975 Reviewed In : 2022	Specification for screw myoma
48	IS 7737 : 1975 Reviewed In : 2022	Specification for forceps punch cervical biopsy
49	IS 7964 : 1992 Reviewed In : 2022	Obstetric instruments - Forceps caesarean section haemostasis green - Armytage pattern - Shape and dimensions First Revision
50	IS 7981 (Part 1) : 1976 Reviewed In : 2022	Instruments Tuboplasty - Part I Occluder Cervical Shirodkar s Pattern
51	IS 7981 (Part 2) : 1976 Reviewed In : 2022	Specification For Instruments Tuboplasty - Part II Cannula Shirodkar s Pattern
52	IS 7981 (Part 3) : 1976 Reviewed In : 2022	Instruments Tuboplasty - Part III Guide Shirodkar s Pattern
53	IS 7981 (Part 4) : 1976 Reviewed In : 2022	Instruments Tuboplasty - Part IV Probe Single Ended Shirodkar s Pattern
54	IS 7981 (Part 5) : 1976 Reviewed In : 2022	Instruments Tuboplasty - Part V Probe Double-Ended Shirodkar s Pattern
55	IS/ISO 8009 : 2014 ISO 8009 : 2014 Reviewed In : 2023 ISO 8009 : 2014	Mechanical contraceptives - Reusable natural and silicone rubber contraceptive diaphragms - Requirements and tests First Revision
56	IS 8313 : 1977 Reviewed In : 2022	Specification for cannula flexible karman type
57	IS 8459 : 1977 Reviewed In : 2022	Specification for menstrual regulation syringe
58	IS 9756 : 1981 Reviewed In : 2022	Specification for cups vacuum extraction