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

AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12)	16th Meeting	04th September 2024 Wednesday **02:30 PM**
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=mbd86c0e2a215de443f4f27097bf7069e **Meeting Number**: 2512 474 7302 **Password**: Mhd12@2-2024		

Chairperson	**Lt Gen Sunil Kant** In-Personal Capacity
Member Secretary	**Ms. Uroosa Warsi** Scientist 'C'/Deputy Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards

ITEM 0 GENERAL

0.1 Welcome Address by Head (MHD)/Member Secretary

0.2 Opening Remarks by Chairperson

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 15th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) held on 29th May 2024 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD/12/A-2.15 dated 02nd June 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 Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) is as follows:

(a) To formulate Indian Standards for: -

- Hospital equipment used in OPD wards and operation theaters such as Sterilizers, Incubators, hospital furniture, and operation tables etc.
- Surgical disposable products like Transfusion, infusion and injection equipment etc., and devices for administration of medical products and intravascular catheters.

(b) To coordinate with the work of: -

- ISO/TC 76 (P): Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use
- ISO/TC 84 (P): Devices for administration of medicinal products and catheters
- ISO/TC 198 (P): Sterilization of health care products
- IEC/PC 130 (P): Cold Storage Equipment for Medical Use

(c) The following working panels have been created.

S. No.	Working Panels
1)	MHD 12 : P1 - Gloves
2)	MHD 12 : P2 - Review of Pre 2000 Standards
3)	MHD 12 : P3 - Syringes, Needles and Ampules
4)	MHD 12 : P4 - Catheters
5)	MHD 12 : P5 - Sterilization of Healthcare Products
6)	MHD 12 : P6 - Infusion Equipment
7)	MHD 12 : P7 - Transfusion Equipment
8)	MHD 12 : P8 - Cold Chain Equipment
9)	MHD 12 : P9 - Medical Furniture

The Committee may please note.

2.2 The present composition of Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) along with participation status of members is enclosed at ***Annexure A* (Page 12-13).**

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 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 UNDER PRINT

3.1 The following Draft Indian Standards are currently under print:

Sl. No	Document No.	Title
1)	MHD/12/19717	Blood Donor Couch Specification
2)	MHD/12/19718	Dialysis Chair
3)	MHD/12/22897	Specification for Filter and Filter Chamber for Blood Transfusion
4)	MHD/12/24230	Specification for refrigerator or combined refrigerator and water pack freezer intermittent mains powered - compression cycle- general requirement and test method
5)	MHD/12/24231	Specification for Vaccine carrier - General requirements and test method
6)	MHD/12/25421	Infusion Equipment for Medical Use Part 2 Closures for Infusion Bottles
7)	MHD/12/25422	Infusion Equipment for Medical Use Part 3 Aluminium Caps for Infusion Bottles
8)	MHD/12/25423	Infusion Equipment for Medical Use Part 5 Burette Infusion Sets for Single Use Gravity Feed

9)	MHD/12/25424	Infusion Equipment for Medical Use Part 6 Freeze Drying Closures for Infusion Bottles
10)	MHD/12/25425	Infusion Equipment for Medical Use Part 7 Caps Made of Aluminium-Plastics Combinations for Infusion Bottles
11)	MHD/12/25426	Infusion equipment for medical use Part 8 Infusion sets for single use with pressure infusion apparatus
12)	MHD/12/25428	Infusion Equipment for Medical Use Part 9 Fluid Lines for Single Use with Pressure Infusion Equipment
13)	MHD/12/25429	Infusion Equipment for Medical Use Part 10 Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment
14)	MHD/12/25430	Infusion Equipment for Medical Use Part 11 Infusion Filters for Single Use with Pressure Infusion Equipment
15)	MHD/12/25431	Infusion Equipment for Medical Use Part 12 Check Valves for Single Use
16)	MHD/12/25432	Infusion Equipment for Medical Use Part 13 Graduated Flow Regulators for Single Use with Fluid Contact
17)	MHD/12/25433	Infusion Equipment for Medical Use Part 14 Clamps and Flow Regulators for Transfusion and Infusion Equipment without Fluid Contact
18)	MHD/12/25434	Infusion Equipment for Medical Use Part 15 Light-Protective Infusion Sets for Single Use
19)	MHD/12/25435	Aseptic Processing of Health Care Products Part 3 Lyophilization
20)	MHD/12/25436	Aseptic Processing of Health Care Products Part 4 Clean-in-Place Technologies
21)	MHD/12/25437	Aseptic Processing of Health Care Products Part 5 Sterilization in Place
22)	MHD/12/25439	Aseptic Processing of Health Care Products Part 6 Isolator Systems
23)	MHD/12/25440	Aseptic Processing of Health Care Products Part 7 Alternative Processes for Medical Devices and Combination Products
24)	MHD/12/25441	Hypodermic Needles for Single Use Colour Coding for Identification (First Revision)
25)	MHD/12/25443	Medical Devices Transfusion Set and Blood Bag Compatibility Test Method
26)	MHD/12/25444	Sterile Packaged Ready for Filling Glass Cartridges
27)	MHD/12/25445	Medical Devices Non-Electrically Driven Portable Infusion Devices

28)	MHD/12/25446	Sterilization of Health Care Products Microbiological Methods Part 3 Bacterial Endotoxin Testing
29)	MHD/12/25448	Stainless Steel Needle Tubing for the Manufacture of Medical Devices Requirements and Test Methods
30)	MHD/12/25449	Intravascular Catheters Sterile and Single-Use Catheters Part 1 General Requirements Second Revision
31)	MHD/12/25583	Intravascular Catheters Sterile and Single-Use Catheters Part 4 Balloon Dilatation Catheters (Second Revision)
32)	MHD/12/25584	Intravascular Catheters Sterile and Single-Use Catheters Part 7 Peripherally Inserted Central Catheters
33)	MHD/12/25585	Sterilization of Health Care Products Radiation Substantiation of Selected Sterilization Dose: Method VDmaxSD
34)	MHD/12/25586	Sterilization of Health Care Products Moist Heat Requirements for the Development Validation and Routine Control of a Sterilization Process for Medical Devices
35)	MHD/12/25589	Sterile Hypodermic Syringes for Single Use Part 4 Syringes with Re-use Prevention Feature

The Committee may kindly note.

ITEM 4 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

4.1 There are currently no standards/amendments for approval for finalization.

ITEM 5 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

5.1

Sl. No.	ISO No.	ISO Title	Remarks
1)	ISO 11608-1:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems	Part 2 of this standard is already adopted and in Part 2 reference is made to Part 1
2)	ISO 4802-1:2023	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification	Earlier version of this standard has been revised by ISO. As earlier version is already adopted, it needs to be harmonized with latest version
3)	ISO 4802-2:202	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part	

	3	2: Determination by flame spectrometry and classification	
4)	ISO 11040-4:2024	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	

The Committee may kindly deliberate.

5.2 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 6 DRAFT UNDER PREPARATION

6.1 Working drafts on two new subjects have been received.

S. No.	Title
1)	Walk-in-Freezer Specification
2)	Vaccine Refrigerator or Combined Refrigerator and Water-Pack Freezer Powered by Solar Direct Drive System General Requirements and Testing Methods

The Committee may kindly deliberate.

6.2 Commenting on P-Drafts by Members of Technical Committee

6.2.1 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.

6.2.2 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.

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

The Committee may kindly note.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

7.1 The following comments were received on IS 15354 (Part 1): 2023 'Single Use Medical Examination Gloves Part 1 Gloves Made from Rubber Latex or Rubber Solution — Specification (*Second Revision*)'

Sr No.	GOVT OF INDIA RULES-VIOLATION	IRGMA Submissions
1	Govt of India- Central Pollution Control Board has issued a letter vide their F. No CP-23/1/2021-WM-I-HO-1903 dated 27/05/2024 directives to implement, in compliance to Bio-Medical Waste Management Rules2016. It indicated the phase out the use of chlorinated gloves by the 27th March 2019, in compliance to Bio-Medical Waste Management (Amendment) Rules2016.	Violation of GOVT OF INDIA Notification - Banned Chlorinated Gloves The clause 2.1 of the bio medical waste management, item 3, mentions that "Phase out use of chlorinated plastic bags and gloves by 27/3/2019." Also clause 5.1.1 of rules states that as per the provisions under BMW Management Rules 2016, "To phase out the Chlorinated gloves by 27THMarch 2019'
2	State Govt of Govt of India -West Bengal Pollution Control Board, vide Memo No. 146/IS-74/2001 (Pt.-IX) dt 20.06.2024.	State Pollution Control Board, has issued directives -not allowing imports in Violation of Guidelines- Banned Chlorinated Gloves - being dealt in a serious manner with heavy penal actions
3	Central Pollution Control Board has issued a letter vide their F. No CP-23/1/2021-WM-I-HO-1898 dated 03/06/2024 – to Tamil Nadu Pollution Control Board to phase out the use of chlorinated gloves, in compliance to Biomedical Waste Management Rules2016.	CPCB, has issued directives -for not allowing imports in Violation of Guidelines- Banned Chlorinated Gloves - being imported by importers of medical devices.

The Committee may kindly deliberate.

ITEM 8 NEW SUBJECTS

8.1 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 a thrust area which should take into consideration the standards development required in the given context keeping in view the social, environmental and economic consideration.

Two new subjects were allocated to interns, working drafts have been received.

Sl. No.	Title
1)	Fowler bed
2)	Burn sheet

The Committee may kindly deliberate.

8.2 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.

Sl. No.	Name of Equipment
1)	Plasma Sterilizer
2)	PM Line
3)	3-way stop cock
4)	Dome kit with flushing system
5)	Coronary microcatheter
6)	E.P. Catheters (multipolar and uni directional and bi-directional)
7)	Mother and child catheter assembly
8)	CSE Set
9)	Epidural Set (Adult and Paediatric)
10)	Spinal Needle (Adult and Paediatric)
11)	ETO sterilisation system
12)	Physiodispenser
13)	Dialysis Chair
14)	Cell Separator (Apheresis machine)
15)	Hydraulic Bed

The Committee may kindly deliberate and decide.

ITEM 9 TECHNICAL ISSUES

9.1 There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 10 INTERNATIONAL ACTIVITIES

10.1 Participating (P) Membership in ISO/IEC

10.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 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/IEC are given below:

Sl. No.	Liaison Committee of ISO	Type of Membership
1)	ISO/TC 76 'Transfusion, infusion and injection and blood processing equipment for medical and pharmaceutical use'	Participating Member
2)	ISO/TC 84 'Devices for administration of medicinal product and catheters'	Participating Member
3)	ISO/TC 198 'Sterilization of health care products'	Participating Member
4)	IEC/PC 130 'Cold Storage Equipment for Medical Use'	Participating Member

10.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and other documents circulated by ISO/IEC seeking votes/comments. The members should carefully examine the documents taking into consideration the nation's interests and send the comments to BIS keeping in mind that if these ISO/IEC 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.

10.2 Harmonization of Indian Standards with International Standards

10.2.1 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.

10.2.2 The list of Standards published by the TCs and SCs of ISO/TC/76, ISO/TC 84 and ISO/TC 198 along with their status of adoption is given at ***Annexure B*** ***(Page 14-30)***.

The Committee may kindly deliberate and recommend the Standards to be adopted as Indian Standards.

ITEM 11 PROGRAMME OF WORK

11.1 The present Programme of Work of Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

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

Stage	No. of Documents
Under Print	35
Under Development	06

ITEM 12 REVIEW OF INDIAN STANDARDS

12.1 Review of pre-2000 Standards

12.1.1 All the Indian Standards published before the year 2000 need to be reviewed for revision/withdrawal/archived 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
91	0	1	84	84	0

12.1.2 The list of the above Indian Standards at various stages is given at ***Annexure C*** ***(Page 31-35)***.

The Committee may kindly review.

12.2 Review of Indian Standards as per 5-year cycle

12.2.1 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.

12.2.2 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.

12.2.3 The list of such Indian Standards which are due for review in 2024-25 is given at ***Annexure D*** ***(Page 36)***.

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

ITEM 13 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

13.1 There are currently no issues related to previous meeting.

The Committee may kindly note.

ITEM 14 DATE AND PLACE OF NEXT MEETING

14.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 12 is scheduled on 27th November 2024.

Quarter	**Q1** **Apr-June 2024**	**Q2** **July-Sept 2024**	**Q3** **Oct-Dec 2024**	**Q4** **Jan-Mar 2025**
Date	29th May 2024, Wednesday	04th Sept 2024, Wednesday	27th Nov 2024, Wednesday	5th Feb 2025, Wednesday

ITEM 15 ANY OTHER BUSINESS

ANNEXURE A
(*Clause 2.2*)

COMPOSITION OF HOSPITAL EQUIPMENT AND SURGICAL DISPOSABLE PRODUCTS SECTIONAL COMMITTEE, MHD 12

Sl. No.	Organization	Member Name	14th Meeting	15Th Meeting
1)	In Individual Capacity	Lt. Gen Sunil Kant	1	1
2)	3M India Limited, Bengaluru	Ms. Kavitha Kulkarni	1	1
		Ms. Prabha Hegde		
3)	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri Asok Kumar Raghavan Nair	1	1
		Shri Parveen Jain		
4)	Association of Indian Medical Device Industry, New Delhi	Shri Ravi Abraham	1	1
		Shri Rajiv Nath		
5)	B Medical Systems India Private Limited, New Delhi	Shri Kishor Tukaram Kaniche	1	0
		Shri Anshuman Tuli		
6)	B. Braun Medical India Private Limited, New Delhi	Shri Vivek Veerbhan	1	1
		Ms. Ishita Dhingra		
7)	Boston Scientific India Private Limited, Gurugram	Shri Prashanth Prabhakar	0	1
		Shri Dev Chopra		
8)	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	1	1
		Ms. Shyamni Sasidharan		
9)	ESIC Dental College and Hospital, Delhi	Dr. Mansi Atri	1	0
		Dr. Nagraj M		
10)	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri Praveen Kumar Sharma	1	1
		Shri Upinder Vishen		
11)	Indian Rubber Gloves Manufacturers Association, New Delhi	Shri Manmohan Singh Gulati	1	1
		Shri Vikas Anand		

12)	Johnson and Johnson Private Limited, Mumbai	Shri Hemant Sonawane	1	1
13)	Kalam Institute of Health Technology, Vishakhapatnam	Shri Amit Sharma Shri Mohan Ragul	1	1
14)	Kanam Latex India Private Limited, Kottayam	Shri Donald S.K. Shri Abraham C. Jacob	1	1
15)	Microtrol Sterilisation Services Private Limited, Mumbai	Shri Bansidhar S. Dhurandhar Shri Manoj Mishra	1	1
16)	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)	Mr. Hitesh Kumar Mr. Shivley Sageer	1	1
17)	Post Graduate Institute of Medical Education and Research, Chandigarh	Shri Sanjeev Sharma Ms. Shweta Talati Dr. Navneet Dhaliwal	0	1
18)	Shriram Institute for Industrial Research, Delhi	Shri Manish Rawat Shri Sanjay Rajput	1	1
19)	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A. Shri V M Shajahan	1	1
20)	In Personal Capacity	Shri Kulveen Singh Bali	-	1

ANNEXURE B
(*Clause 10.2.2*)

ISO STANDARDS PUBLISHED UNDER ISO/TC 76

Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use

Scope:

Standardization of containers (such as infusion bottles and bags, injection vials, ampoules, glass cylinders, cartridges, pre fillable syringes, etc.) application systems (such as giving sets, non-electrically driven portable infusion devices, blood collection systems, etc.) and accessories for infusion, transfusion, injection and blood processing in blood banks, terms, definitions, requirements and test methods for these devices, specifications and test methods for quality and performance of their materials and components (such as elastomeric closures, caps and ports, pipettes, etc.) and quality management systems for primary packaging materials.

Sl. No.	ISO No.	ISO Title	Status of adoption	Corresponding IS/Doc No.
1)	ISO 719:2020	Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification	Adopted	IS 2303 (Part 1/Sec 1) : 2021/ISO 719 : 2020
2)	ISO 720:2020	Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification	Adopted	IS 2303 (Part 1/Sec 2) : 2021/ISO 720 : 2020
3)	ISO 1135-3:2016	Transfusion equipment for medical use — Part 3: Blood-taking sets for single use	Adopted	IS/ISO 1135-3 : 2016
4)	ISO 1135-4:2015	Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed	Adopted	IS/ISO 1135-4 : 2015
5)	ISO 1135-5:2015	Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus	Under adoption	MHD/12/17339
6)	ISO 3749:2022	Glass syringes — Determination of extractable tungsten	Not adopted	

7)	ISO 3826-1:2019	Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers	Adopted	IS/ISO 3826-1 : 2019
8)	ISO 3826-1:2019/Amd 1:2023	Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers — Amendment 1	Adopted	
9)	ISO 3826-2:2008	Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets	Adopted	IS/ISO 3826-2 : 2008
10)	ISO 3826-3:2006	Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features	Adopted	IS/ISO 3826-3 : 2006
11)	ISO 3826-4:2015	Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features	Adopted	IS/ISO 3826-4 : 2015
12)	ISO 4802-1:2023	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification	Old edition adopted	IS 2303 (Part 2) : 2018/ISO 4802-1 : 2016
13)	ISO 4802-2:2023	Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification	Old edition adopted	IS 2303 (Part 3) : 2018/ISO 4802-2 : 2016
14)	ISO 6710:2017	Single-use containers for human venous blood specimen collection	Adopted	IS 10867 : 2018/ISO 6710 : 2017
15)	ISO 6717:2021	In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood	Adopted	IS 18723 : 2024/ISO 6717 : 2021
16)	ISO 8362-1:2018	Injection containers and accessories — Part 1: Injection vials made of glass tubing	Adopted	IS 1984 (Part 1) : 2023/ISO 8362-1 : 2018
17)	ISO 8362-2:2024	Injection containers and accessories — Part 2: Closures for injection vials	Under adoption & Old edition adopted	MHD/12/25953 IS 1984 (Part 4) : 2023/ISO 8362-2 : 2015
18)	ISO 8362-3:2001	Injection containers and accessories — Part 3: Aluminium caps for injection vials	Adopted	IS 1984 (Part 3) : 2023/ISO 8362-3 : 2001

19)	ISO 8362-4:2011	Injection containers and accessories — Part 4: Injection vials made of moulded glass	Adopted	IS 1984 (Part 2) : 2023
20)	ISO 8362-5:2016	Injection containers and accessories — Part 5: Freeze drying closures for injection vials	Adopted	IS 1984 (Part 5) : 2024/ ISO 8362-5 : 2016
21)	ISO 8362-6:2010	Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials	Adopted	IS 1984 (Part 6) : 2024/ ISO 8362-6 : 2010
22)	ISO 8362-7:2006	Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part	Not adopted	
23)	ISO 8536-1:2011	Infusion equipment for medical use — Part 1: Infusion glass bottles	Adopted	IS/ISO 8536-1 : 2011
24)	ISO 8536-2:2023	Infusion equipment for medical use — Part 2: Closures for infusion bottles	Under adoption	MHD/12/25421
25)	ISO 8536-3:2009	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles	Under adoption	MHD/12/25422
26)	ISO 8536-3:2009/Amd 1:2022	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles — Amendment 1	Under adoption	*MHD/12/25422
27)	ISO 8536-4:2019	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed	Adopted	IS/ISO 8536-4 : 2019
28)	ISO 8536-5:2004	Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed	Under adoption	MHD/12/25423
29)	ISO 8536-6:2016	Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles	Under adoption	MHD/12/25424
30)	ISO 8536-7:2009	Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles	Under adoption	MHD/12/25425
31)	ISO 8536-8:2015	Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus	Under adoption	MHD/12/25426
32)	ISO 8536-9:2015	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment	Under adoption	MHD/12/25428
33)	ISO 8536-10:2015	Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment	Under adoption	MHD/12/25429

34)	ISO 8536-11:2015	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment	Under adoption	MHD/12/25430
35)	ISO 8536-12:2021	Infusion equipment for medical use — Part 12: Check valves for single use	Under adoption	MHD/12/25431
36)	ISO 8536-13:2016	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact	Under adoption	MHD/12/25432
37)	ISO 8536-14:2016	Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact	Under adoption	MHD/12/25433
38)	ISO 8536-15:2022	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use	Under adoption	MHD/12/25434
39)	ISO 8536-15:2022/Amd 1:2023	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use — Amendment 1	Under adoption	*MHD/12/25434
40)	ISO 8871-1:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates	Not adopted	
41)	ISO 8871-2:2020	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization	Not adopted	
42)	ISO 8871-3:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count	Not adopted	
43)	ISO 8871-3:2003/Amd 1:2018	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count — Amendment 1	Not adopted	
44)	ISO 8871-4:2006	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods	Not adopted	
45)	ISO 8871-5:2016	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing	Not adopted	
46)	ISO 8872:2022	Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods	Not adopted	
47)	ISO 9187-1:2010	Injection equipment for medical use — Part 1: Ampoules for injectables	Adopted	IS 15537 : 2021/ISO 9187-1 : 2010

48)	ISO 9187-2:2010	Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules	Adopted	IS 15537 (Part 2) : 2023/ISO 9187-2 : 2010
49)	ISO 11040-1:2015	Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges	Adopted	IS/ISO 11040-1 : 2015
50)	ISO 11040-2:2011	Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges	Adopted	IS/ISO 11040-2 : 2011
51)	ISO 11040-3:2012	Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges	Adopted	IS/ISO 11040-3 : 2012
52)	ISO 11040-4:2024	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Old edition adopted	IS/ISO 11040-4 : 2015
53)	ISO 11040-5:2012	Prefilled syringes — Part 5: Plunger stoppers for injectables	Adopted	IS/ISO 11040-5 : 2012
54)	ISO 11040-6:2019	Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Not adopted	
55)	ISO 11040-7:2024	Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling	Not adopted	
56)	ISO 11040-8:2016	Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes	Not adopted	
57)	ISO 11418-1:2016	Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing glass bottles	Adopted	IS/ISO 11418-1 : 2016
58)	ISO 11418-2:2016	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups	Adopted	IS/ISO 11418-2 : 2016
59)	ISO 11418-2:2016/Amd 1:2017	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups — Amendment 1	Adopted	IS/ISO 11418-2 : 2016
60)	ISO 11418-3:2016	Containers and accessories for pharmaceutical preparations — Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms	Adopted	IS/ISO 11418-3 : 2016
61)	ISO 11418-3:2016/Amd 1:2017	Containers and accessories for pharmaceutical preparations — Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms — Amendment 1	Adopted	IS/ISO 11418-3 : 2016

62)	ISO 11418-4:2005	Containers and accessories for pharmaceutical preparations — Part 4: Tablet glass bottles	Not adopted	
63)	ISO 11418-5:2015	Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies	Adopted	IS/ISO 11418-5 : 2015
64)	ISO 11418-7:2016	Containers and accessories for pharmaceutical preparations — Part 7: Screw-neck vials made of glass tubing for liquid dosage forms	Adopted	IS/ISO 11418-7 : 2016
65)	ISO 13926-1:2018	Pen systems — Part 1: Glass cylinders for pen-injectors for medical use	Adopted	IS/ISO 13926-1 : 2018
66)	ISO 13926-2:2017	Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use	Adopted	IS/ISO 13926-2 : 2017
67)	ISO 13926-3:2019	Pen systems — Part 3: Seals for pen-injectors for medical use	Adopted	IS 18293 (Part 3) : 2023/ISO 13926-3 : 2019
68)	ISO 15010:1998	Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods	Not adopted	
69)	ISO 15137:2005	Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods	Not adopted	
70)	ISO 15375:2010	Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods	Not adopted	
71)	ISO 15378:2017	Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)	Adopted	IS/ISO 15378 : 2017
72)	ISO 15378:2017/Amd 1:2024	Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP) — Amendment 1: Climate action changes	Not adopted	
73)	ISO 15747:2018	Plastic containers for intravenous injections	Adopted	IS 18735 : 2024/ISO 15747 : 2018
74)	ISO 15759:2005	Medical infusion equipment — Plastics caps with inserted elastomeric liner for	Not adopted	

		containers manufactured by the blow-fill-seal (BFS) process		
75)	ISO/TR 19727:2017	Medical devices — Pump tube spallation test — General procedure	Not adopted	
76)	ISO 21881:2019	Sterile packaged ready for filling glass cartridges	Under adoption	MHD/12/25444
77)	ISO 21882:2019	Sterile packaged ready for filling glass vials	Not adopted	
78)	ISO 22413:2021	Transfer sets for pharmaceutical preparations — Requirements and test methods	Not adopted	
79)	ISO/TS 23128:2019	Medical devices — Transfusion set and blood bag compatibility test method	Under adoption	MHD/12/25443
80)	ISO 24072:2023	Aerosol bacterial retention test method for air-inlet filter on administration devices	Not adopted	
81)	ISO 24166-1:2022	Snap-on bottles for metering pumps — Part 1: Tubular glass	Not adopted	
82)	ISO 24166-2:2022	Snap-on bottles for metering pumps — Part 2: Moulded glass	Not adopted	
83)	ISO 24166-3:2022	Snap-on bottles for metering pumps — Part 3: Plastic	Not adopted	
84)	ISO 28620:2020	Medical devices — Non-electrically driven portable infusion devices	Under adoption	MHD/12/25445

ISO/ TC 84

ISO STANDARDS PUBLISHED UNDER ISO/TC 84

Devices for administration of medicinal products and catheters

Scope:

Standardization of the performance of metered devices and supplies intended for administration of medicinal products, and standardization of syringes, needles and catheters.

Sl. No.	ISO No.	ISO Title	Status of adoption	Corresponding IS/Doc No.
1)	ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification	Under adoption & Old edition adopted	MHD/12/25441 IS 16004 : 2013/ISO 6009: 1992
2)	ISO 7864:2016	Sterile hypodermic needles for single use — Requirements and test methods	Adopted	IS 10654 : 2018/ISO 7864 : 2016
3)	ISO 7886-1:2017	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	Adopted	IS 10258 (Part 1) : 2022/ISO 7886-1 : 2017
4)	ISO 7886-2:2020	Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps	Adopted	IS 10258 (Part 2) : 2024/ISO 7886-2 : 2020
5)	ISO 7886-3:2020	Sterile hypodermic syringes for single use — Part 3: Auto-disabled syringes for fixed-dose immunization	Adopted	IS 10258 (Part 3) : 2021/ISO 7886-3 : 2020
6)	ISO 7886-4:2018	Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature	Under adoption	MHD/12/25589
7)	ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin	Adopted	IS 12227 : 2020/ISO 8537 : 2016
8)	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Under adoption	MHD/12/25448
9)	ISO 10555-1:2023	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements	Under adoption & Old edition adopted	MHD/12/25449 IS/ISO 10555-1 : 2013

10)	ISO 10555-3:2013	Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters	Adopted	IS/ISO 10555-3 : 2013
11)	ISO 10555-4:2023	Intravascular catheters — Sterile and single-use catheters — Part 4: Balloon dilatation catheters	Under adoption & Old edition adopted	MHD/12/25583 IS/ISO 10555-4 : 2013
12)	ISO 10555-5:2013	Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters	Adopted	IS/ISO 10555-5 : 2013
13)	ISO 10555-6:2015	Intravascular catheters — Sterile and single-use catheters — Part 6: Subcutaneous implanted ports	Adopted	IS 18292 (Part 6) : 2023/ISO 10555-6 : 2015
14)	ISO 10555-6:2015/Amd 1:2019	Intravascular catheters — Sterile and single-use catheters — Part 6: Subcutaneous implanted ports — Amendment 1	Adopted	IS 18292 (Part 6) : 2023/ISO 10555-6 : 2015
15)	ISO 10555-7:2023	Intravascular catheters — Sterile and single-use catheters — Part 7: Peripherally inserted central catheters	Under adoption	MHD/12/25584
16)	ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires	Adopted	IS 18529 : 2024/ISO 11070 : 2014
17)	ISO 11070:2014/Amd 1:2018	Sterile single-use intravascular introducers, dilators and guidewires — Amendment 1	Adopted	
18)	ISO 11608-1:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems	Not adopted	
19)	ISO 11608-2:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 2: Double-ended pen needles	Under adoption	MHD/12/25590
20)	ISO 11608-3:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths	Not adopted	
21)	ISO 11608-4:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 4: Needle-based injection systems containing electronics	Not adopted	

22)	ISO 11608-5:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions	Not adopted	
23)	ISO 11608-6:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 6: On-body delivery systems	Not adopted	
24)	ISO 11608-7:2016	Needle-based injection systems for medical use — Requirements and test methods — Part 7: Accessibility for persons with visual impairment	Not adopted	
25)	ISO 14972:1998	Sterile obturators for single use with over-needle peripheral intravascular catheters	Not adopted	
26)	ISO/TR 19244:2014	Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters	Not adopted	
27)	ISO 20069:2019	Guidance for assessment and evaluation of changes to drug delivery systems	Under adoption	MHD/12/23900
28)	ISO 20072:2009	Aerosol drug delivery device design verification — Requirements and test methods	Not adopted	
29)	ISO 20695:2020	Enteral feeding systems — Design and testing	Not adopted	
30)	ISO 20696:2018	Sterile urethral catheters for single use	Adopted	IS 18288 : 2023/ISO 20696 : 2018
31)	ISO 20697:2018	Sterile drainage catheters and accessory devices for single use	Adopted	IS 18451 : 2023/ISO 20697 : 2018
32)	ISO 20698:2018	Catheter systems for neuraxial application — Sterile and single-use catheters and accessories	Adopted	IS 18478 : 2024/ISO 20698 : 2018
33)	ISO 21649:2023	Needle-free injection systems for medical use — Requirements and test methods	Not adopted	
34)	ISO 23217:2024	Injection systems for self-administration by paediatric patients — Requirements and guidelines for design	Not adopted	

35)	ISO 23907-1:2019	Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers	Adopted	IS 18200 (Part 1) : 2024
36)	ISO 23907-2:2019	Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers	Not adopted	
37)	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	Under adoption	MHD/21/22114

ISO/TC 198

ISO STANDARDS PUBLISHED UNDER ISO/TC 198

Sterilization of health care products

Scope:

Standardization of processes and equipment for sterilization of health care products.

Sl. No.	ISO No.	ISO Title	Status of adoption	Corresponding IS /Doc No.
1)	ISO/TS 5111:2022	Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products	Adopted	IS 18618 : 2024/ ISO/TS 5111 : 2022
2)	ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Adopted	IS/ISO 11135 : 2014
3)	ISO 11135:2014 /Amd 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	Not adopted	
4)	ISO 11137-1:2006	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	Adopted	IS/ISO 11137-1 : 2006
5)	ISO 11137-1:2006/Amd 1:2013	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1	Adopted	
6)	ISO 11137-1:2006/Amd 2:2018	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 2: Revision to 4.3.4 and 11.2	Adopted	
7)	ISO 11137-2:2013	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	Adopted	IS/ISO 11137-2 : 2013

8)	ISO 11137-2:2013/Amd 1:2022	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose — Amendment 1	Adopted	
9)	ISO 11137-3:2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control	Adopted	IS/ISO 11137-3 : 2017
10)	ISO/TS 11137-4:2020	Sterilization of health care products — Radiation — Part 4: Guidance on process control	Adopted	IS 18294 (Part 4) : 2023/ISO/TS 11137-4 : 2020
11)	ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements	Adopted	IS/ISO 11138-1 : 2017
12)	ISO 11138-2:2017	Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes	Adopted	IS/ISO 11138-2 : 2017
13)	ISO 11138-3:2017	Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes	Adopted	IS/ISO 11138-3 : 2017
14)	ISO 11138-4:2017	Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes	Adopted	IS/ISO 11138-4 : 2017
15)	ISO 11138-5:2017	Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	Adopted	IS/ISO 11138-5 : 2017
16)	ISO 11138-7:2019	Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results	Adopted	IS 18469 (Part 7) : 2023/ISO 11138-7 : 2019
17)	ISO 11138-8:2021	Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator	Adopted	IS 18469 (Part 8) : 2023/ISO 11138-8 : 2021
18)	ISO 11139:2018	Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards	Adopted	IS 18240 : 2023/ISO 11139 : 2018
19)	ISO 11139:2018/Amd 1:2024	Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Amendment 1: Amended and additional terms and definitions	Not adopted	

20)	ISO 11140-1:2014	Sterilization of health care products — Chemical indicators — Part 1: General requirements	Adopted	IS 18466 (Part 1) : 2023
21)	ISO 11140-3:2007	Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	Adopted	IS/ISO 11140-3 : 2007
22)	ISO 11140-3:2007/Cor 1:2007	Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test — Technical Corrigendum 1	Adopted	IS/ISO 11140-3 : 2007
23)	ISO 11140-4:2007	Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	Adopted	IS/ISO 11140-4 : 2007
24)	ISO 11140-5:2007	Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	Adopted	IS/ISO 11140-5 : 2007
25)	ISO 11140-6:2022	Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers	Adopted	IS 18446 (Part 6) : 2024/ ISO 11140-6 : 2022
26)	ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	Adopted	IS/ISO 11607-1 : 2019
27)	ISO 11607-1:2019/Amd 1:2023	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems — Amendment 1: Application of risk management	Not adopted	
28)	ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes	Adopted	IS/ISO 11607-2 : 2019
29)	ISO 11607-2:2019/Amd 1:2023	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes — Amendment 1: Application of risk management	Not adopted	
30)	ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products	Adopted	IS/ISO 11737-1 : 2018
31)	ISO 11737-1:20	Sterilization of health care products — Microbiological methods — Part 1:	Adopted	

	18/Amd 1:2021	Determination of a population of microorganisms on products — Amendment 1		
32)	ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Adopted	IS/ISO 11737-2 : 2019
33)	ISO 11737-3:2023	Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing	Under adoption	MHD/12/25446
34)	ISO 13004:2022	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	Under adoption	MHD/12/25585
35)	ISO 13408-1:2023	Aseptic processing of health care products — Part 1: General requirements	Under adoption & Old edition adopted	MHD/12/25954 IS/ISO 13408-1 : 2008
36)	ISO 13408-2:2018	Aseptic processing of health care products — Part 2: Sterilizing filtration	Adopted	IS/ISO 13408-2 : 2018
37)	ISO 13408-3:2006	Aseptic processing of health care products — Part 3: Lyophilization	Under adoption	MHD/12/25435
38)	ISO 13408-4:2005	Aseptic processing of health care products — Part 4: Clean-in-place technologies	Under adoption	MHD/12/25436
39)	ISO 13408-5:2006	Aseptic processing of health care products — Part 5: Sterilization in place	Under adoption	MHD/12/25437
40)	ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems	Under adoption	MHD/12/25439
41)	ISO 13408-7:2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products	Under adoption	MHD/12/25440
42)	ISO 14160:2020	Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	Under adoption	MHD/12/23985

43)	ISO 14937:2009	Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	Adopted	IS/ISO 14937 : 2009
44)	ISO 15882:2008	Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results	Not adopted	
45)	ISO 15883-1:2006	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	Adopted	IS/ISO 15883-1 : 2006
46)	ISO 15883-1:2006/Amd 1:2014	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests — Amendment 1	Adopted	IS/ISO 15883-1 : 2006
47)	ISO 15883-2:2006	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	Adopted	IS/ISO 15883-2 : 2006
48)	ISO 15883-3:2006	Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	Adopted	IS/ISO 15883-3 : 2006
49)	ISO 15883-4:2018	Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	Adopted	IS 18344 (Part 4) : 2023/ISO 15883-4 : 2018
50)	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	Adopted	IS 18468 (Part 5) : 2024
51)	ISO 15883-6:2011	Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment	Adopted	IS/ISO 15883-6 : 2011
52)	ISO 15883-7:2016	Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment	Not adopted	
53)	ISO/TS 16775:2021	Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2	Adopted	IS 18245 : 2023/ISO/TS 16775 : 2021

54)	ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	Adopted	IS 18742 (Part 1) : 2024/ ISO 17664-1 : 2021
55)	ISO 17664-2:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices	Adopted	IS 18742 (Part 2) : 2024/ISO 17664-2 : 2021
56)	ISO 17665:2024	Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	Under adoption	MHD/12/25586
57)	ISO 18362:2016	Manufacture of cell-based health care products — Control of microbial risks during processing	Not adopted	
58)	ISO 18362:2016 /Amd 1:2022	Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1	Not adopted	
59)	ISO 18472:2018	Sterilization of health care products — Biological and chemical indicators — Test equipment	Not adopted	
60)	ISO/TS 19930:2017	Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6	Adopted	IS 18243 : 2023/ISO/TS 19930 : 2017
61)	ISO 20857:2010	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	Not adopted	
62)	ISO/TS 21387:2020	Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release	Adopted	IS 18244 : 2023/ISO/TS 21387 : 2020
63)	ISO/TS 22421:2021	Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities	Adopted	IS 18287 : 2023/ISO/TS 22421 : 2021
64)	ISO 22441:2022	Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation	Not adopted	

		and routine control of a sterilization process for medical devices		
65)	ISO/TS 22456:2021	Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products	Not adopted	
66)	ISO 25424:2018	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	Not adopted	
67)	ISO 25424:2018 /Amd 1:2022	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1	Not adopted	

ANNEXURE C
(*Clause 12.1.2*)

PRE 2000 STANDARDS

Sl. No.	IS No.	IS Title	Decision taken (if any)
1)	IS 10150 : 1981	Guide for sterilization of medical products	Withdrawn
2)	IS 12050 : 1986	Specification for sterile hypodermic syringes with needle attached for single use	Withdrawn
3)	IS 3235 : 1988	General requirements for syringes for medical use (Second Revision)	Withdrawn
4)	IS 6208 : 1971	Specification for spoons, plastics, measuring, medicine	Withdrawn
5)	IS 9824 (Part 1) : 1996ISO 1135-1	Transfusion equipment for medical use - Specification: Part 1 glass transfusion bottles, closures and caps (First Revision)	Withdrawn
6)	IS 10985 : 1984	Specification for needle, acupuncture	Decision taken to withdraw
7)	IS 1108 : 1975	Specification for pharmaceutical glass containers (Second Revision)	Decision taken to withdraw
8)	IS 11400 : 1985	Specification for hypodermic syringes, interchangeable type for general purposes	Decision taken to withdraw
9)	IS 7455 : 1974	Specification for sterilizer, pressure, hot and cold water	Decision taken to withdraw
10)	IS 13422 : 1992	Disposable surgical rubber gloves specification	Will be superseded by IS 13422:2024
11)	IS 4445 : 1967	Specification for filter and filter chamber for blood transfusion	Will be superseded by MHD/12/22897
12)	IS 5029 : 1979	Specification for bedsteads, hospital, general purposes (First Revision)	Duplicacy
13)	IS 10263 : 1982	Specification for deep fat fryer, single and double pan electrically operated, for large catering establishments	To be withdrawn
14)	IS 10264 : 1982	Specification for trolley, hot food, for hospital and industrial cantee - Ns	To be withdrawn
15)	IS 10783 : 1983	Specification for patient - Lifting devices, mobile, manually operated	To be withdrawn
16)	IS 13115 : 1991	Portable first - Aid kit for general use - Specification	To be withdrawn

17)	IS 14193 : 1994	Ovulation thermometers - Specification	To be withdrawn
18)	IS 3120 : 1999	Baby incubators - Specification (Second Revision)	To be withdrawn
19)	IS 3236 : 1992	Hypodermic syringes for general purposes - Specification (Second Revision)	To be withdrawn
20)	IS 3423 : 1973	Specification for glass containers for transfusion fluids (First Revision)	To be withdrawn
21)	IS 3830 : 1979	Specification for water stills for pyrogen - Free distilled water (Second Revision)	To be withdrawn
22)	IS 3994 : 1993	Bowls,wash - Specification (Second Revision)	To be withdrawn
23)	IS 3997 : 1982	Specification for jars, ointment (First Revision)	To be withdrawn
24)	IS 4034 : 1979	Specification for castors for hospital equipment (First Revision)	To be withdrawn
25)	IS 4363 : 1980	Specification for drip counter E. M. S. pattern (First Revision)	To be withdrawn
26)	IS 5336 : 1969	Specification for back rest	To be withdrawn
27)	IS 5337 : 1969	Specification for cot, dropside, baby, hospital	To be withdrawn
28)	IS 5630 : 1994	Cribs (Cradles), maternity - Specification (First Revision)	To be withdrawn
29)	IS 6877 : 1977	Specification for cabinet, instruments (First Revision)	To be withdrawn
30)	IS 7036 : 1982	Specification for table, postmortem (First Revision)	To be withdrawn
31)	IS 7081 : 1973	Specification for stool, revolving, for hospital use	To be withdrawn
32)	IS 7171 : 1974	Specification for drip counter with filter	To be withdrawn
33)	IS 7523 : 1974	Specification for rubber catheter (Urinary)	To be withdrawn
34)	IS B13115 : 1991	Portable First Aid Kit for General Use (Bi-lingual)	To be withdrawn
35)	IS B14316 : 1995	Swabs, Small, in Bag of 50 (Bi-lingual)	To be withdrawn
36)	IS B8462 : 1977	Sterilizer, Portable, Vertical, Pressure Type (BI-LINGUAL)	To be withdrawn
37)	IS 10603 : 1983	Specification for abdominal belts	Transfer to MHD 03
38)	IS 12173 : 1987	Specification for cervical halter	Transfer to MHD 09

39)	IS 3118 : 1978	Specification for electric bacteriological incubators (First Revision)	Transfer to MHD 10
40)	IS 4455 : 1967	Specification for trolleys, soiled linen	Transfer to MHD 21
41)	IS 6593 : 1972	Specification for electric serological water - Baths	Transfer to MHD 10
42)	IS 6904 : 1973	Specification for receptacle, waste	Transfer to MHD 21
43)	IS 11043 : 1984	Specification for needle, epidural	To be revised
44)	IS 12430 : 1987	Safety code for installation, servicing maintenance and of sterilizers	To be revised
45)	IS 3831 : 1979	Specification for sterilizer, shallow (Dressing Drum)	To be revised
46)	IS 3992 : 1982	Specification for trays, kidney (First Revision)	To be revised
47)	IS 3993 : 1993	Trays, instruments - Specification (Second Revision)	To be revised
48)	IS 4033 : 1968	General requirements for hospital furniture	To be revised
49)	IS 4267 : 1967	Specification for stands, wash hand basin	To be revised
50)	IS 5880 : 1970	Specification for stand, saline - Cum - Irrigator	To be revised
51)	IS 3119 : 1978	Specification for hot air sterilizers (First Revision)	To be revised
52)	IS 3237 (Part 1) : 1985	Specification for special purpose syringes: Part 1 insulin syringes (Second Revision)	To be revised
53)	IS 3237 (Part 2) : 1985	Specification for special purpose syringes: Part 2 tuberculin syringes (Second Revision)	To be revised
54)	IS 3237 (Part 3) : 1985	Specification for special purpose syringes: Part 3 bcg syringes (Second Revision)	To be revised
55)	IS 3237 (Part 4) : 1986	Specification for special purpose syringes: Part 4 vaccine syringe	To be revised
56)	IS 3237 (Part 5) : 1986	Specification for special purpose syringes: Part 5 post operation care syringe (Second Revision)	To be revised
57)	IS 3237 (Part 6) : 1986	Specification for special purpose syringes: Part 6 irrigation syringe	To be revised

58)	IS 3237 (Part 7) : 1986	Specification for special purpose syringe: Part 7 forced feeding syringe	To be revised
59)	IS 3237 (Part 8) : 1986	Specification for special purpose syringes: Part 8 angiography syringe	To be revised
60)	IS 3829 (Part 1) : 1999	Specification for steam sterilizers: Part 1 horizontal cylindrical and horizontal rectangular steam sterilizers, pressure type (For Hospital And Pharmaceutical Use) (Second Revision)	To be revised
61)	IS 3829 (Part 2) : 1978	Specification for steam sterilizers: Part 2 horizontal cylindrical high speed steam sterilizers, pressure type (First Revision)	To be revised
62)	IS 3829 (Part 3) : 1985	Specification for steam sterilizers: Part 3 pressure sterilizers, vertical cylindrical type	To be revised
63)	IS 4035 : 1967	Specification for trolleys, stretcher	To be revised
64)	IS 4036 : 1967	Specification for trolleys, patient	To be revised
65)	IS 4037 : 1967	Specification for stretchers and stretcher carriers	To be revised
66)	IS 4148 : 1989	Surgical rubber gloves - Specification (First Revision)	To be revised
67)	IS 4266 : 1967	Specification for lockers, bedside for hospital use	To be revised
68)	IS 4458 : 1967	Specification for screens, bedside	To be revised
69)	IS 4494 : 1968	Specification for tables, overbed	To be revised
70)	IS 4769 : 1968	Specification for trolley, dressing	To be revised
71)	IS 4787 : 1968	Specification for table, examination	To be revised
72)	IS 5022 : 1989	Sterilizer, instruments, table model (Third Revision)	To be revised
73)	IS 5035 : 1969	Specification for sterilizers, bowl and utensil (Pedal Type)	To be revised
74)	IS 5291 : 1969	Specification for tables, operation, hydraulic, major	To be revised
75)	IS 5631 : 1970	Specification for trolley, instrument, plain and curved	To be revised
76)	IS 6083 : 1971	Specification for table, obstetric, labour	To be revised

77)	IS 6106 : 1971	Specification for tables, operation, hydraulic, minor	To be revised
78)	IS 6328 : 1971	Specification for table, operation, general purposes (Non - Hydraulic)	To be revised
79)	IS 6905 : 1973	Instruments Table, Mayo's Type	To be revised
80)	IS 7083 : 1973	Specification for trolley, medicine	To be revised
81)	IS 7091 : 1973	Specification for lifter, bed, adjustable	To be revised
82)	IS 7099 : 1973	Specification for trolley, dressing drum	To be revised
83)	IS 7350 : 1974	Specification for needles, spinal	To be revised
84)	IS 7378 : 1974	Bed, Fowler's, Hospital	To be revised
85)	IS 7387 : 1974	Needle, Biopsy, Liver, Silverman's Pattern	To be revised
86)	IS 7596 : 1974	Table, Operation, Orthopaedic, Albee's Type	To be revised
87)	IS 8078 : 1976	Specification for table, operation, paediatric	To be revised
88)	IS 8079 : 1976	Specification for table, operation, urological	To be revised
89)	IS 9132 : 1979	Specification for table, operation, folding type	To be revised
90)	IS 9133 : 1979	Specification for trolley for general medical store	To be revised
91)	IS 8462 : 1977	Specification for sterilizer, portable, vertical, pressure type	To be revised

ANNEXURE D

(*Clause 12.2.3*)

STANDARDS DUE FOR REVIEW

Sl. No.	IS Number	IS Title	Due Date	Remarks
1)	IS 12227 : 2020/ISO 8537 : 2016	Sterile Single-Use Syringes, With or Without Needle, for Insulin (*Second Revision*)	March, 2025	Reaffirmed
2)	IS 3120 : 1999	Baby incubators - Specification (*Second Revision*)	April, 2024	To be withdrawn
3)	IS 3829 (Part 1) : 1999	Specification for steam sterilizers: Part 1 horizontal cylindrical and horizontal rectangular steam sterilizers, pressure type (For Hospital and Pharmaceutical Use) (*Second Revision*)	April, 2024	To be revised
4)	IS 3993 : 1993	Trays, instruments - Specification (*Second Revision*)	December, 2024	To be revised
5)	IS 3994 : 1993	Bowls,wash - Specification (*Second Revision*)	December, 2024	To be withdrawn
6)	IS 5022 : 1989	Sterilizer, instruments, table model (*Third Revision*)	May, 2024	To be revised
7)	IS 5630 : 1994	Cribs (Cradles), maternity - Specification (*First Revision*)	April, 2024	To be withdrawn
8)	IS/ISO 10555-4 : 2013	Sterile, single - Use intravascular catheters: Part 4 balloon dilatation catheters	December, 2024	New version under adoption (MHD/12/25583)