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)	17th Meeting	17 December 2024 Tuesday **02:30 PM**
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=m446bb92cf7bf8bb549029a20af26ecba **Meeting Number**: 2513 540 8073 **Password**: Mhd12@3-2024		

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 Member Secretary

0.2 Opening Remarks by Chairperson

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the 16th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) held on 04 September 2024 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD/12/A-2.16 dated 14 October 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

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 11-12).***

2.3 The Working Panels under Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) are enclosed at ***Annexure B*** ***(Page 13-15)***.

2.4 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.

2.5 The following member was consecutively absent in last two meetings held on 29 May 2024 and 04 September 2024:

Sl. No.	Organisation
1)	ESIC Dental College and Hospital, Delhi

2.5.1 The above member has become inactive by virtue of non-participation in consecutive meetings and has been removed.

The Committee may please note.

2.6 The following organization has requested BIS for representation in the Committee:

Sl. No.	Organisation	Nomination
1)	Baxter R&D, Bengaluru	Shri Hari Babu S

2.6.1 The CV is attached at ***Annexure C*** ***(Page 16-21).***

The Committee may kindly deliberate.

2.7 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
2)	MHD/12/19718	Dialysis chair
3)	MHD/12/22897	Filter and filter chamber for blood transfusion — Specification (*first revision*)
4)	MHD/12/24230	Refrigerator or combined refrigerator and water-pack freezer intermittent mains powered — Compression cycle — General requirements and test methods
5)	MHD/12/24231	Vaccine carriers — General requirements and test methods
6)	MHD/12/25422	Infusion equipment for medical use Part 3 Aluminium caps for infusion bottles
7)	MHD/12/25424	Infusion equipment for medical use Part 6 Freeze drying closures for infusion bottles
8)	MHD/12/25426	Infusion equipment for medical use Part 8 Infusion sets for single use with pressure infusion apparatus

9)	MHD/12/25434	Infusion equipment for medical use Part 15 Light-protective infusion sets for single use
10)	MHD/12/25435	Aseptic processing of health care products Part 3 Lyophilization

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 8536-13:2024	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact	Earlier versions of these standards have been revised by ISO. As earlier versions are already adopted, they need to be harmonized with latest versions
2)	ISO 15883-1:2024	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	
3)	ISO 15883-2:2024	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices	
4)	ISO 15883-3:2024	Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	

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 The following indigenous subject drafts are under preparation.

S. No.	Title	Remarks
1)	Fowler bed	As per the decision of the committee in the last meeting, the working drafts on "Fowler bed" and "Burn sheet" were circulated to all members via email dated 06 December 2024. The last date for submitting comments was 15 December 2024.
2)	Burn sheet	

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 13422 : 2024/ISO 10282 : 2023 'Single-use sterile rubber surgical gloves — Specification (*first revision*)'.

Proposed Change	Justification
Clause 7.4 Sterility **7.4.1** Gloves shall be sterilized. The nature of the sterilization process shall be disclosed on request. **7.4.2** Gloves when tested in accordance with IS/ISO 11737-1: 2018, the Total Microbial count (Total number of bacteria and fungi) (CFU /100 cm^2) shall be Absent.	The Clause 7.4 of IS 13422:2024/ ISO 10282:2023 explicitly does not specify any test method for checking the sterility of gloves which in our opinion is an essential requirement, the product being a sterile one. Similar requirement exist for IS 3319: 1995 BLADES, SURGICAL, DETACHABLE (BARD PARKER TYPE) AND HANDLES — where each batch of the sterilized blades shall meet the requirements of sterility, when tested in accordance with IS 10150: 1981." **[IS 10150: 1981 has been superseded by IS/ISO 11737-1: 2018].**

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.

8.2 Status of New Subjects

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

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 D*** ***(Page 22-39)***.

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	10
Under Development	08

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	Review Complete	Under Development	Under Print	Remaining	Under Progress (out of the remaining)	Pending
91	6	0	1	84	84	0

12.1.2 The list of the above Indian Standards at various stages is given at ***Annexure E*** ***(Page 40-44)***.

The Committee may deliberate.

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 is as follows:

Sl. No.	IS Number	IS Title	Remarks
1)	IS 10654 : 2018/ISO 7864 : 2016	Sterile hypodermic needles for single use — Requirements and test methods (*fourth revision*)	Current version of ISO
2)	IS 16097 : 2013	Sterile single use scalp vein (Winged Needle) infusion set	-
3)	IS 15113 : 2002	Clinical electrical thermometers with maximum device — Specification	-

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

ITEM 13 ACTION TAKEN REPORT ON THE MINUTES OF PREVIOUS MEETING/ ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

13.1 Action taken report on the minutes of the previous meeting is given at ***Annexure F*** ***(Page 45-47)***.

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 05 February 2025.

Quarter	**Q1** **Apr-June 2024**	**Q2** **July-Sept 2024**	**Q3** **Oct-Dec 2024**	**Q4** **Jan-Mar 2025**
Date	29 May 2024, Wednesday	04 Sept 2024, Wednesday	17 Dec 2024, Tuesday	5 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	Participation Status	
			15th Meeting	16th Meeting
1)	In Individual Capacity	Lt. Gen Sunil Kant VSM	1	1
2)	3M India Limited, Bengaluru	Dr. Prabha Hegde	1	1
		Ms. Kavitha Kulkarni		
3)	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri Asok Kumar Raghavan Nair	1	0
		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	0	1
		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	1	1
		Shri Dev Chopra		
8)	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	1	0
		Ms. Shyamni Sasidharan		
9)	Dupont, India	Shri Vishnu Shankar Vyas	-	-
		Shri Rajdeep Singh Grewal		
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	0

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

ANNEXURE B
(*Clause* 2.3)

WORKING PANELS UNDER HOSPITAL EQUIPMENT AND SURGICAL

DISPOSABLE PRODUCTS SECTIONAL COMMITTEE, MHD 12

Composition of Gloves Panel [MHD 12 : P1]

S. No.	Organization	Member Name	Role
1)	In Individual Capacity	Lt. Gen Sunil Kant VSM	Convener
2)	Association of Indian Medical Device Industry, New Delhi	Shri Ravi Abraham	Expert
3)	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	Expert
4)	Central Drugs Standard Control Organization, New Delhi	Ms. Shyamni Sasidharan	Expert
5)	Indian Rubber Gloves Manufacturers Association, New Delhi	Shri Manmohan Singh Gulati	Expert
6)	Indian Rubber Gloves Manufacturers Association, New Delhi	Shri Vikas Anand	Expert
7)	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Navneet Dhaliwal	Expert
8)	Post Graduate Institute of Medical Education and Research, Chandigarh	Shri Sanjeev Sharma	Expert

Composition of Review of Pre 2000 Standards Panel [MHD 12 : P2]

S. No.	Organization	Member Name	Role
1)	3M India Limited, Bengaluru	Dr. Prabha Hegde	Convener
2)	3M India Limited, Bengaluru	Ms. Kavitha Kulkarni	Expert
3)	Association of Indian Medical Device Industry, New Delhi	Shri Rajiv Nath	Expert
4)	B. Braun Medical India Private Limited, New Delhi	Shri Vivek Veerbhan	Expert
5)	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Shweta Talati	Expert
6)	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Navneet Dhaliwal	Expert
7)	In Personal Capacity	Shri Kulveen Singh Bali	Expert

Syringes, Needles and Ampules Panel [MHD 12 : P3]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener
2)	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri Praveen Kumar Sharma	Expert

Catheters Panel [MHD 12 : P4]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener

Sterilization of Healthcare Products Panel [MHD 12 : P5]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener
2)	3M India Limited, Bengaluru	Ms. Kavitha Kulkarni	Expert
3)	Dupont, India	Shri Vishnu Shankar Vyas	Expert
4)	Shriram Institute for Industrial Research, Delhi	Dr. Sanjay Rajput	Expert
5)	In Personal Capacity	Shri Kulveen Singh Bali	Expert

Infusion Equipment Panel [MHD 12 : P6]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener

Transfusion Equipment Panel [MHD 12 : P7]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener
2)	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.	Expert

Cold Chain Equipment Panel [MHD 12 : P8]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener
2)	B Medical Systems India Private Limited, New Delhi	Shri Anshuman Tuli	Expert
3)	National Institute of Health and Family Welfare, New Delhi (NCCVMRC)	Shri Shivley Sageer	Expert

Medical Furniture Panel [MHD 12 : P9]

S. No.	Organization	Member Name	Role
1)	TBD	TBD	Convener

ANNEXURE C
(*Clause* 2.6)

CV OF NOMINEE

Hari Babu S, MSc
Address : 303, Prathika Enclave, 1st Cross,
Coconut Garden Layout , Kodigehalli Main Road,
KR Puram, Bangalore -5600 36, India
Mobile : +91 -9940955354
E-mail : Haribabu.sudharsanam@gmail.com

OBJECTIVE

Seeking a challenging role that requires knowledge, skills, and experience in the following areas:

1. Biological safety evaluation associated with medical devices and component materials, and process changes in accordance with ISO 10993 and other national and international standards.
2. Toxicological risk assessment on extractable and leachable profile of the medical devices.
3. Biocompatibility testing strategy for new products and sustaining products that include studies using in vitro culture and in vivo animal models.
4. Compliance with internal standards and regulatory requirements to ensure the efficacy and safety of medical devices.

PROFESSIONAL SUMMARY

Biocompatibility and Toxicology Specialist with 13+ years of experience in biological safety evaluation and toxicological risk assessment of medical devices as per ISO 10993 standards. Proven history as a successful biocompatibility scientist from a combination of industry experience working in the medical device industry for new product development and life cycle management of sustaining products and hands-on experience working in a CRO as a study director for different classes of medical devices. Having an in-depth technical knowledge of the ISO 10993 standards and regulatory requirements in the US and EU. Expert in developing biocompatibility testing strategy, biological evaluation plan, executing the biocompatibility testing, and authoring biological evaluation report for successful regulatory submissions. Member of BIS ISO 10993 committee, India. Having an excellent record as an international speaker/trainer in ISO 10993 standards to leading manufacturers and regulatory bodies like Saudi FDA (SFDA), HOYA Optics-Thailand, and LG Chem-Korea and as a speaker in national conferences like “Medical Device Regulatory and Quality Summit”, in 2017 and 2022, India and organized multiple 10993 Biocompatibility workshops in India.

PROFESSIONAL EXPERIENCE

Organization	Designation	Duration
Baxter Healthcare	Research Scientist II	Dec 2023-Present
Baxter Healthcare	Research Scientist I	Aug 2018-Nov 2023
UL India Private Limited	Biocompatibility Engineer	May 2017-Jul 2018
GLR Laboratories Pvt Ltd	Senior Scientist	May 2010-Apr 2017

EDUCATION

Advanced Comprehensive Course in Toxicology, American College of Toxicology, 2020 Master of Science (Biotechnology) - Vinayaka Mission University, India, 2013 Bachelor of Technology (Biotechnology), Anna University, India, 2008

RESPONSIBILITIES

Current Employer: Baxter Innovations and Business Solutions Private Limited

Position: Research Scientist - Biocompatibility Lead, Infusion Therapies and Technologies, Medical Products & Therapies

1. Perform gap analysis and execute biocompatibility testing to remediate the gaps to meet the state-of-the-art requirements.
2. Perform biocompatibility/toxicology impact assessments for the process changes in the existing products based on the biological risk management process.
3. Collaborate with cross-functional team members (engineering, extractable and leachable, materials, sterility, etc.) to determine a comprehensive testing strategy.
4. Monitoring biocompatibility studies in external CROs, technical review of study protocols, and test reports.
5. Authoring BEP and BER for regulatory submissions.
6. Effectively coach and mentor junior team members.
7. Develop biocompatibility testing strategies to qualify new products and materials per global standards. Ensure compliance with regulatory guidelines such as ISO, ASTM, and USP 87 and 88.
8. Develop preclinical regulatory summaries for DHF files, USA FDA 510 K submissions, and CE Mark.

9. Utilize Siemens Team Center Unified global material management system (GMMS) for biocompatibility testing, product development, and registration support.
10. Develop project schedules; provide estimates and timelines to meet project milestones.
11. Attend Project Review and Core team meetings.
12. Implement the use of ISO10993-1, regional pharmacopeia, 21 CFR Part 58 Good Laboratory Practices for Non-Clinical Laboratory Studies, and/or other regulatory guidance documents to qualify Baxter products.
13. Performing toxicology risk assessment of extractable and leachable in line with ISO 10993-17.

Previous Employer: Underwriters Laboratories Private Limited, Bangalore, India

Position: Biocompatibility Engineer

1. Conduct international and national biocompatibility training, workshops, seminars, and webinars.
2. Design and recommend testing strategies to global customers.
3. Biological safety assessment of medical devices to issue "Declaration of Compliance" (DoC) to ISO 10993.
4. Genotoxicology assessment of leachable from medical devices using the TTC concept based on ICH M7 guidelines.
5. Recommend toxicology testing requirements for medical devices as per ISO 10993 standards.
6. Design study protocol for toxicology testing as per regulatory needs.
7. Monitor toxicology studies and review reports.
8. Recommend toxicology testing requirements of medical device packaging materials as per ASTM standards.
9. Recommend toxicology testing requirements of raw materials like plastics and elastomers as per USP 87 and 88.
10. Conduct a literature search to support toxicology risk assessment of implant devices.
11. Perform toxicology risk assessment of medical devices, pharmaceutical containers, bioreactors, etc., based on extractable and leachable testing.
12. Establishment of allowable limits of leachable substances from medical devices based on ISO 10993-Part 17.
13. Design chemical characterization test methods for medical devices in consultation with a chemist and material scientist followed by a risk assessment of toxicology.
14. Risk management of medical devices as per ISO 14971.

Previous Employer: GLR Laboratories Pvt Ltd, India

Position: Senior Scientist

1. To scientifically conduct the non-clinical toxicity studies in compliance with the Principles of GLP, regulatory guidelines and animal welfare guidelines.
2. To plan, conduct and monitor the studies required to be conducted in the toxicology department.
3. To take part and monitor the study related activities like study designing, study plan writing, experimental procedures, data recording and analysis, report writing and archiving.
4. To prepare and review SOPs required for day to day working in the areas of direct concern and to review and provide inputs in the SOPs of the other related groups.
5. To conduct, participate, supervise, and ensure the validation studies are conducted wherever/whenever required in the group.
6. To ensure, in case of multisite studies, as Study Director, that the delegated Phase of the study is being performed in compliance with the Principles of GLP.

Study Director

1. Conducted more than 300 biocompatibility studies in a GLP Set up as a Study director.
2. Supported different class of devices like implants, catheters, disposables, dialyzers, stents, IOLS, respiratory and cardiovascular devices.
3. Hands on experience in cytotoxicity, irritation, sensitization, acute/sub chronic systemic toxicity, implantation, genotoxicity, hemocompatibility and pyrogen testing of medical devices.
4. To act as the single point of study control and take the responsibility for the overall conduct of the study and for its final report.
5. To approve the study plan and any amendments to the study plan by dated signatures.
6. To ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study.
7. To ensure that study plans and amendments and Standard Operating Procedures are available to study personnel.
8. To ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study.
9. To ensure that the procedures specified in the study plan are followed and assess and document the impact of any deviations from the study plan on the quality and integrity of the study and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study.
10. To ensure that all raw data generated is fully documented and recorded.

11. To sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with the Principles of Good Laboratory Practice.
12. To ensure that after the study's completion (including termination), the study plan, the final report, raw data, and supporting material are archived.

CERTIFICATIONS, CONFERENCES, AND TRAINING

1. Conference Speaker "Regulatory Compliance in Biocompatibility Testing" - Medical Device Evolution: Advancements and Innovations Webinar, 5 Sep 2024, Virtual.
2. Attended 42nd Annual Conference of the Society of Toxicology, India (STOX 2023), Calicut, Kerela, Nov 23-25, 2023.
3. Attended EUROTOX 2023 Conference - 57th Congress of the European Societies of Toxicology, Ljubljana, Slovenia. 10th -13th Sep 2023.
4. Conference Speaker- "Current Challenges in Biocompatibility Testing of Medical Devices"- 6th Annual Medical Device Regulatory and Quality Summit, 2022, India
5. Course-Certificate of completion in "Dose-Response Assessment Boot Camp" by TERA-Toxicology Excellence for Risk Assessment, 2022, India
6. Conference Participant-MedTech Summit Virtual Event - Biocompatibility of Medical Devices, 2020, Virtual event, UK.
7. Course-Advanced Comprehensive Virtual Course in Toxicology, American College of Toxicology, 2020
8. International training - Biocompatibility testing requirements for medical devices, HOYA Optics-Thailand, 2019
9. Conference Participant-Asian Federation of Laboratory Animal Science (AFLAS) Conference, 2018, Bangalore, India.
10. Training-Quality Management System Training: ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories, 2018, UL India.
11. Speaker-National Workshop- "Biological safety evaluation of medical devices", 2018, New Delhi, India.
12. Speaker-National Workshop- "Biological safety evaluation of medical devices", 2018, Ahmedabad, India.
13. Course-Certificate of completion in "Train the Trainer" course, 2017, India
14. Conference Speaker-Strategy for biocompatibility evaluation of medical devices, 2nd Annual Medical Device Regulatory and Quality Summit, 2017, India

15. International training - “Overview about 10993 standards and requirements” to Saudi FDA (SFDA), 2017, Saudi Arabia.
16. International training - Implementation of Biocompatibility requirements based on ISO 10993, LG Chem - UL joint seminar, 2017, South Korea

PUBLICATION

B.Brabu, S.Haribabu, M.Revathy, S.Anitha, M.Thangapandiyan, K.R.Navanethakrishnan, C.Gopalakrishnan, S.S.Murugan, T.S.Kumaravel. Biocompatibility studies on lanthanum oxide nanoparticles. Toxicology Research. 2015; 15, 43-30.

ANNEXURE D
(*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.

S. 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 *(Adopted by CHD 10)*
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 *(Adopted by CHD 10)*
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	Adopted	IS 18474 (Part 5) : 2024/ISO 1135-5 : 2015
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:	Adopted	IS/ISO 3826-1 : 2019

		Conventional containers		
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 *(Adopted by CHD 10)*
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 *(Adopted by CHD 10)*
14)	ISO 6710:2017	Single-use containers for human venous blood specimen collection	Adopted	IS 10867 : 2018/ISO 6710 : 2017 *(Adopted by MHD 10)*
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/TR 8417:2024	Risk management of particulate contamination for devices with intravascular access	Not adopted	
24)	ISO 8536-1:2011	Infusion equipment for medical use — Part 1: Infusion glass bottles	Adopted	IS/ISO 8536-1 : 2011
25)	ISO 8536-2:2023	Infusion equipment for medical use — Part 2: Closures for infusion bottles	Adopted	IS 18879 (Part 2) : 2024/ISO 8536-2 : 2023
26)	ISO 8536-3:2009	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles	Under adoption	MHD/12/25422
27)	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
28)	ISO 8536-4:2019	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed	Adopted	IS/ISO 8536-4 : 2019
29)	ISO 8536-5:2004	Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed	Adopted	IS 18879 (Part 5) : 2024/ISO 8536-5 : 2004
30)	ISO 8536-6:2016	Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles	Under adoption	MHD/12/25424
31)	ISO 8536-7:2009	Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles	Adopted	IS 18879 (Part 7) : 2024/ISO 8536-7 : 2009
32)	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
33)	ISO 8536-9:2015	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment	Adopted	IS 18879 (Part 9) : 2024/ISO 8536-9 : 2015

34)	ISO 8536-10:2015	Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment	Adopted	IS 18879 (Part 10) : 2024/ISO 8536-10 : 2015
35)	ISO 8536-11:2015	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment	Adopted	IS 18879 (Part 11) : 2024/ISO 8536-11 : 2015
36)	ISO 8536-12:2021	Infusion equipment for medical use — Part 12: Check valves for single use	Adopted	IS 18879 (Part 12) : 2024/ISO 8536-12 : 2021
37)	ISO 8536-13:2024	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact	Old edition adopted	IS 18879 (Part 13) : 2024/ISO 8536-13 : 2016
38)	ISO 8536-14:2016	Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact	Adopted	IS 18879 (Part 14) : 2024/ISO 8536-14 : 2016
39)	ISO 8536-15:2022	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use	Under adoption	MHD/12/25434
40)	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
41)	ISO 8871-1:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates	Not adopted	
42)	ISO 8871-2:2020	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization	Not adopted	
43)	ISO 8871-3:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count	Not adopted	
44)	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	
45)	ISO 8871-4:2006	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods	Not adopted	
46)	ISO 8871-5:2016	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing	Not adopted	
47)	ISO 8872:2022	Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials —	Not adopted	

		General requirements and test methods		
48)	ISO 9187-1:2010	Injection equipment for medical use — Part 1: Ampoules for injectables	Adopted	IS 15537 : 2021/ISO 9187-1 : 2010
49)	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
50)	ISO 11040-1:2015	Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges	Adopted	IS/ISO 11040-1 : 2015
51)	ISO 11040-2:2011	Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges	Adopted	IS/ISO 11040-2 : 2011
52)	ISO 11040-3:2012	Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges	Adopted	IS/ISO 11040-3 : 2012
53)	ISO 11040-4:2024	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Under adoption & Old edition adopted	MHD/12/27038 IS/ISO 11040-4 : 2015
54)	ISO 11040-5:2012	Prefilled syringes — Part 5: Plunger stoppers for injectables	Adopted	IS/ISO 11040-5 : 2012
55)	ISO 11040-6:2019	Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Not adopted	
56)	ISO 11040-7:2024	Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling	Not adopted	
57)	ISO 11040-8:2016	Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes	Not adopted	
58)	ISO 11418-1:2016	Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing glass bottles	Adopted	IS/ISO 11418-1 : 2016
59)	ISO 11418-2:2016	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups	Adopted	IS/ISO 11418-2 : 2016
60)	ISO 11418-2:2016/Amd 1:2017	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups — Amendment 1	Adopted	
61)	ISO 11418-3:2016	Containers and accessories for pharmaceutical preparations — Part 3:	Adopted	IS/ISO 11418-3 : 2016

		Screw-neck glass bottles (veral) for solid and liquid dosage forms		
62)	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	
63)	ISO 11418-4:2005	Containers and accessories for pharmaceutical preparations — Part 4: Tablet glass bottles	Not adopted	
64)	ISO 11418-5:2015	Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies	Adopted	IS/ISO 11418-5 : 2015
65)	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
66)	ISO 13926-1:2018	Pen systems — Part 1: Glass cylinders for pen-injectors for medical use	Adopted	IS/ISO 13926-1 : 2018
67)	ISO 13926-2:2017	Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use	Adopted	IS/ISO 13926-2 : 2017
68)	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
69)	ISO 15010:1998	Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods	Not adopted	
70)	ISO 15137:2005	Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods	Not adopted	
71)	ISO 15375:2010	Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods	Not adopted	
72)	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
73)	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	

74)	ISO 15747:2018	Plastic containers for intravenous injections	Adopted	IS 18735 : 2024/ISO 15747 : 2018
75)	ISO 15759:2005	Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process	Not adopted	
76)	ISO/TR 19727:2017	Medical devices — Pump tube spallation test — General procedure	Not adopted	
77)	ISO 21881:2019	Sterile packaged ready for filling glass cartridges	Adopted	IS 18872 : 2024/ISO 21881 : 2019
78)	ISO 21882:2019	Sterile packaged ready for filling glass vials	Not adopted	
79)	ISO 22413:2021	Transfer sets for pharmaceutical preparations — Requirements and test methods	Not adopted	
80)	ISO/TS 23128:2019	Medical devices — Transfusion set and blood bag compatibility test method	Adopted	IS 18855 : 2024/ISO/TS 23128 : 2019
81)	ISO 24072:2023	Aerosol bacterial retention test method for air-inlet filter on administration devices	Not adopted	
82)	ISO 24166-1:2022	Snap-on bottles for metering pumps — Part 1: Tubular glass	Not adopted	
83)	ISO 24166-2:2022	Snap-on bottles for metering pumps — Part 2: Moulded glass	Not adopted	
84)	ISO 24166-3:2022	Snap-on bottles for metering pumps — Part 3: Plastic	Not adopted	
85)	ISO 28620:2020	Medical devices — Non-electrically driven portable infusion devices	Adopted	IS 18871 : 2024/ISO 28620 : 2020

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.

S. 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	Adopted	IS 16004 : 2024/ISO 6009 : 2016
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	Adopted	IS 10258 (Part 4) : 2024/ISO 7886-4 : 2018
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	Adopted	IS 18866 : 2024/ISO 9626 : 2016
9)	ISO 10555-1:2023	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements	Adopted	IS 18292 (Part 1) : 2024/ISO 10555-1 : 2023
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	Adopted	IS 18292 (Part 4) : 2024/ISO 10555-4 : 2023
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	
15)	ISO 10555-7:2023	Intravascular catheters — Sterile and single-use catheters — Part 7: Peripherally inserted central catheters	Adopted	IS 18292 (Part 7) : 2024/ISO 10555-7 : 2023
16)	ISO 10555-8:2024	Intravascular catheters — Sterile and single-use catheters — Part 8: Catheters for extracorporeal blood treatment	Not adopted	
17)	ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires	Adopted	IS 18529 : 2024/ISO 11070 : 2014
18)	ISO 11070:2014/Amd 1:2018	Sterile single-use intravascular introducers, dilators and guidewires — Amendment 1	Not adopted	
19)	ISO 11608-1:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems	Under adoption	MHD/12/27039
20)	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
21)	ISO 11608-3:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths	Not adopted	
22)	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	
23)	ISO 11608-5:2022	Needle-based injection systems for medical use — Requirements and test	Not adopted	

		methods — Part 5: Automated functions		
24)	ISO 11608-6:2022	Needle-based injection systems for medical use — Requirements and test methods — Part 6: On-body delivery systems	Not adopted	
25)	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	
26)	ISO 14972:1998	Sterile obturators for single use with over-needle peripheral intravascular catheters	Not adopted	
27)	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	
28)	ISO 20069:2019	Guidance for assessment and evaluation of changes to drug delivery systems	Adopted	IS 18744 : 2024/ISO 20069 : 2019
29)	ISO 20072:2009	Aerosol drug delivery device design verification — Requirements and test methods	Not adopted	
30)	ISO 20695:2020	Enteral feeding systems — Design and testing	Not adopted	
31)	ISO 20696:2018	Sterile urethral catheters for single use	Adopted	IS 18288 : 2023/ISO 20696 : 2018
32)	ISO 20697:2018	Sterile drainage catheters and accessory devices for single use	Adopted	IS 18451 : 2023/ISO 20697 : 2018
33)	ISO 20698:2018	Catheter systems for neuraxial application — Sterile and single-use catheters and accessories	Adopted	IS 18478 : 2024/ISO 20698 : 2018
34)	ISO 21649:2023	Needle-free injection systems for medical use — Requirements and test methods	Not adopted	
35)	ISO 23217:2024	Injection systems for self-administration by paediatric patients — Requirements and guidelines for design	Not adopted	
36)	ISO 23907-1:2019	Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers	Adopted	IS 18200 (Part 1) : 2024 *(Adopted by MHD 21)*
37)	ISO 23907-	Sharps injury protection — Requirements	Not	

	2:2019	and test methods — Part 2: Reusable sharps containers	adopted	
38)	ISO 23908:2024	Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods	Old edition adopted	IS 18481 : 2024/ISO 23908 : 2011 *(Adopted by MHD 21)*

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.

S. 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-	Sterilization of health care products —	Adopted	

	2:2013/Amd 1:2022	Radiation — Part 2: Establishing the sterilization dose — Amendment 1		
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-	Sterilization of health care products —	Adopted	IS 18466 (Part

	1:2014	Chemical indicators — Part 1: General requirements		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	
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:	Adopted	IS/ISO 11737-1 : 2018

		Determination of a population of microorganisms on products		
31)	ISO 11737-1:2018/Amd 1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products — Amendment 1	Adopted	
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	Adopted	IS 18863 (Part 3) : 2024/ISO 11737-3 : 2023
34)	ISO 13004:2022	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	Adopted	IS 18880 : 2024/ISO 13004 : 2022
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	Adopted	IS 18881 (Part 4) : 2024/ISO 13408-4 : 2005
39)	ISO 13408-5:2006	Aseptic processing of health care products — Part 5: Sterilization in place	Adopted	IS 18881 (Part 5) : 2024/ISO 13408-5 : 2006
40)	ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems	Adopted	IS 18881 (Part 6) : 2024/ISO 13408-6 : 2021
41)	ISO 13408-7:2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products	Adopted	IS 18881 (Part 7) : 2024/ISO 13408-7 : 2012
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	Adopted	IS 18730 : 2024/ISO 14160 : 2020

		medical devices		
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 15883-1:2024	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	Old edition adopted	IS/ISO 15883-1 : 2006
46)	ISO 15883-2:2024	Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices	Old edition adopted	IS/ISO 15883-2 : 2006
47)	ISO 15883-3:2024	Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	Old edition adopted	IS/ISO 15883-3 : 2006
48)	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
49)	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	Adopted	IS 18468 (Part 5) : 2024
50)	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
51)	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	
52)	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
53)	ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of	Adopted	IS 18742 (Part 1) : 2024/ ISO 17664-1 : 2021

		medical devices — Part 1: Critical and semi-critical medical devices		
54)	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
55)	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	Adopted	IS 18319 : 2024/ISO 17665 : 2024
56)	ISO 18362:2016	Manufacture of cell-based health care products — Control of microbial risks during processing	Not adopted	
57)	ISO 18362:2016/ Amd 1:2022	Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1	Not adopted	
58)	ISO 18472:2018	Sterilization of health care products — Biological and chemical indicators — Test equipment	Not adopted	
59)	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
60)	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	
61)	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
62)	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
63)	ISO 22441:2022	Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Not adopted	
64)	ISO/TS 22456:2021	Sterilization of healthcare products — Microbiological methods— Guidance on	Not adopted	

		conducting bioburden determinations and tests of sterility for biologics and tissue-based products		
65)	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	
66)	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 E

(*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 4148 : 1989	Surgical rubber gloves - Specification (First Revision)	Decision taken to withdraw
11)	IS 13422 : 1992	Disposable surgical rubber gloves specification	Will be superseded by IS 13422:2024
12)	IS 4445 : 1967	Specification for filter and filter chamber for blood transfusion	Will be superseded by MHD/12/22897
13)	IS 5029 : 1979	Specification for bedsteads, hospital, general purposes (First Revision)	To be withdrawn (Duplicacy)
14)	IS 10263 : 1982	Specification for deep fat fryer, single and double pan electrically operated, for large catering establishments	To be withdrawn
15)	IS 10264 : 1982	Specification for trolley, hot food, for hospital and industrial canteens	To be withdrawn
16)	IS 10783 : 1983	Specification for patient - Lifting devices, mobile, manually operated	To be withdrawn

17)	IS 13115 : 1991	Portable first - Aid kit for general use - Specification	To be withdrawn
18)	IS 14193 : 1994	Ovulation thermometers - Specification	To be withdrawn
19)	IS 3120 : 1999	Baby incubators - Specification (Second Revision)	To be withdrawn
20)	IS 3236 : 1992	Hypodermic syringes for general purposes - Specification (Second Revision)	To be withdrawn
21)	IS 3423 : 1973	Specification for glass containers for transfusion fluids (First Revision)	To be withdrawn
22)	IS 3830 : 1979	Specification for water stills for pyrogen - Free distilled water (Second Revision)	To be withdrawn
23)	IS 3994 : 1993	Bowls,wash - Specification (Second Revision)	To be withdrawn
24)	IS 3997 : 1982	Specification for jars, ointment (First Revision)	To be withdrawn
25)	IS 4034 : 1979	Specification for castors for hospital equipment (First Revision)	To be withdrawn
26)	IS 4363 : 1980	Specification for drip counter E. M. S. pattern (First Revision)	To be withdrawn
27)	IS 5336 : 1969	Specification for back rest	To be withdrawn
28)	IS 5337 : 1969	Specification for cot, dropside, baby, hospital	To be withdrawn
29)	IS 5630 : 1994	Cribs (Cradles), maternity - Specification (First Revision)	To be withdrawn
30)	IS 6877 : 1977	Specification for cabinet, instruments (First Revision)	To be withdrawn
31)	IS 7036 : 1982	Specification for table, postmortem (First Revision)	To be withdrawn
32)	IS 7081 : 1973	Specification for stool, revolving, for hospital use	To be withdrawn
33)	IS 7171 : 1974	Specification for drip counter with filter	To be withdrawn
34)	IS 7523 : 1974	Specification for rubber catheter (Urinary)	To be withdrawn
35)	IS B13115 : 1991	Portable First Aid Kit for General Use (Bi-lingual)	To be withdrawn
36)	IS B14316 : 1995	Swabs, Small, in Bag of 50 (Bi-lingual)	To be withdrawn
37)	IS B8462 : 1977	Sterilizer, Portable, Vertical, Pressure Type (BI-LINGUAL)	To be withdrawn
38)	IS 3237 (Part 1) : 1985	Specification for special purpose syringes: Part 1 insulin syringes (Second Revision)	To be withdrawn

39)	IS 3237 (Part 2) : 1985	Specification for special purpose syringes: Part 2 tuberculin syringes (Second Revision)	To be withdrawn
40)	IS 3237 (Part 3) : 1985	Specification for special purpose syringes: Part 3 bcg syringes (Second Revision)	To be withdrawn
41)	IS 3237 (Part 4) : 1986	Specification for special purpose syringes: Part 4 vaccine syringe	To be withdrawn
42)	IS 3237 (Part 5) : 1986	Specification for special purpose syringes: Part 5 post operation care syringe (Second Revision)	To be withdrawn
43)	IS 3237 (Part 6) : 1986	Specification for special purpose syringes: Part 6 irrigation syringe	To be withdrawn
44)	IS 3237 (Part 7) : 1986	Specification for special purpose syringe: Part 7 forced feeding syringe	To be withdrawn
45)	IS 3237 (Part 8) : 1986	Specification for special purpose syringes: Part 8 angiography syringe	To be withdrawn
46)	IS 10603 : 1983	Specification for abdominal belts	Transfer to MHD 03
47)	IS 12173 : 1987	Specification for cervical halter	Transfer to MHD 09
48)	IS 3118 : 1978	Specification for electric bacteriological incubators (First Revision)	Transfer to MHD 10
49)	IS 4455 : 1967	Specification for trolleys, soiled linen	Transfer to MHD 21
50)	IS 6593 : 1972	Specification for electric serological water - Baths	Transfer to MHD 10
51)	IS 6904 : 1973	Specification for receptacle, waste	Transfer to MHD 21
52)	IS 11043 : 1984	Specification for needle, epidural	To be revised
53)	IS 12430 : 1987	Safety code for installation, servicing maintenance and of sterilizers	To be revised
54)	IS 3831 : 1979	Specification for sterilizer, shallow (Dressing Drum)	To be revised
55)	IS 3992 : 1982	Specification for trays, kidney (First Revision)	To be revised
56)	IS 3993 : 1993	Trays, instruments - Specification (Second Revision)	To be revised
57)	IS 4033 : 1968	General requirements for hospital furniture	To be revised

58)	IS 4267 : 1967	Specification for stands, wash hand basin	To be revised
59)	IS 5880 : 1970	Specification for stand, saline - Cum - Irrigator	To be revised
60)	IS 3119 : 1978	Specification for hot air sterilizers (First Revision)	To be revised
61)	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
62)	IS 3829 (Part 2) : 1978	Specification for steam sterilizers: Part 2 horizontal cylindrical high speed steam sterilizers, pressure type (First Revision)	To be revised
63)	IS 3829 (Part 3) : 1985	Specification for steam sterilizers: Part 3 pressure sterilizers, vertical cylindrical type	To be revised
64)	IS 4035 : 1967	Specification for trolleys, stretcher	To be revised
65)	IS 4036 : 1967	Specification for trolleys, patient	To be revised
66)	IS 4037 : 1967	Specification for stretchers and stretcher carriers	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 F
(*Clause 13.1*)

ACTION TAKEN ON THE MINUTES OF PREVIOUS MEETING OF MHD 12

<table>
<tr><th>Sl. No.</th><th>Item No.</th><th>Committee decision</th><th>Summary of action taken</th></tr>
<tr><td>1.</td><td>2.1</td><td>Accepted the participation request of the following members in the working panels.

<table>
<tr><th>Sl. No.</th><th>Working Panels</th><th>Members</th></tr>
<tr><td>1)</td><td>MHD 12 : P1 - Gloves</td><td>• Shri Manmohan Singh Gulati</td></tr>
<tr><td>2)</td><td>MHD 12 : P3 - Syringes, Needles and Ampules</td><td>• Shri Praveen Kumar Sharma</td></tr>
<tr><td>3)</td><td>MHD 12 : P5 - Sterilization of Healthcare Products</td><td>• Dr. Sanjay Rajput
• Shri Kulveen Singh Bali
• Ms. Kavitha Kulkarni
• Shri Vishnu Shankar Vyas</td></tr>
<tr><td>4)</td><td>MHD 12 : P7 - Transfusion Equipment</td><td>• Shri Manoj A.</td></tr>
<tr><td>5)</td><td>MHD 12 : P8 - Cold Chain Equipment</td><td>• Shri Anshuman Tuli
• Shri Shivley Sageer</td></tr>
</table></td><td>The members have been included in the composition of the respective working panels.</td></tr>
<tr><td>2.</td><td>2.3</td><td>Accepted the co-option request of Shri Vishnu Shankar Vyas (E.I. DuPont India Pvt Ltd).</td><td>DuPont India has been included in the committee composition.</td></tr>
<tr><td>3.</td><td>5.1</td><td>a) To adopt the following ISO standard and wide-circulate the document for a period of one month.

<table>
<tr><th>ISO No.</th><th>ISO Title</th></tr>
<tr><td>ISO 11608-1:2022</td><td>Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems</td></tr>
</table></td><td>The document was wide circulated on 05 December 2024.

Last date for sharing comments is 02 January 2025.</td></tr>
</table>

<table>
<tr><th>Sl. No.</th><th>Item No.</th><th>Committee decision</th><th>Summary of action taken</th></tr>
<tr><td></td><td></td><td>b) To adopt the following ISO standard to revise the existing older version and wide-circulate the document for a period of one month:

<table><tr><th>ISO No.</th><th>ISO Title</th></tr><tr><td>ISO 11040-4:2024</td><td>Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling</td></tr></table></td><td>The document was wide circulated on 05 December 2024.

Last date for sharing comments is 02 January 2025.</td></tr>
<tr><td>4.</td><td>6.1</td><td>To circulate the following P-draft to all members for a period of 30 days.

<table><tr><th>S. No.</th><th>Title</th></tr><tr><td>1)</td><td>Walk-in-Freezer Specification</td></tr><tr><td>2)</td><td>Vaccine Refrigerator or Combined Refrigerator and Water-Pack Freezer Powered by Solar Direct Drive System General Requirements and Testing Methods</td></tr></table></td><td>Technical corrections are needed in the documents prior to circulation. It is recommended that these documents be assigned to MHD 12 : P8 – Cold Chain Equipment Panel for detailed deliberation and final review.</td></tr>
<tr><td rowspan="2">5.</td><td rowspan="2">7.1</td><td>a) To recommend IS 15354 (Part 1): 2023 ‘Single use medical examination gloves Part 1 Gloves made from rubber latex or rubber solution — Specification (second revision)’ to MHD 12 : P1 – Gloves panel for a detailed analysis and further deliberation.</td><td>The meeting of 'MHD 12: P1 – Gloves panel' is tentatively scheduled for 16 December 2024.</td></tr>
<tr><td>b) To withdraw IS 4148:1989 ‘Surgical rubber gloves — Specification (first revision)’</td><td>Currently with Division Council for approval.</td></tr>
<tr><td>6.</td><td>8.2</td><td>To circulate the following draft to all members for their inputs.

<table><tr><th>Sl. No.</th><th>Title</th></tr></table></td><td>The documents were circulated to all the members via email dated 06 December 2024.</td></tr>
</table>

Sl. No.	Item No.	Committee decision	Summary of action taken
		1) Fowler bed 2) Burn sheet	
7.	12.1	To circulate the list of pre-2000 standards, along with the recommendations of the working panel, to all members for a period of 10 days	The list was circulated to all the members via email dated 14 October 2024.