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

DRAFT AGENDA

Sectional Committee	Meeting No:	Date, Day & Time
Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12)	14	12 March 2024 Tuesday 11:00 AM
via Webex platform **Meeting Link**: https://bismanak.webex.com/bismanak/j.php?MTID=m21f71115c889cdb5c5f7d4f794c2f966 **Meeting Number**: 2521 668 2718 **Password**: Mhd@12		
Chairperson Lt Gen Sunil Kant (Retired)	**Member Secretary** Ms. Harshada Ganesh Kadam, Sc-B	

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 13th meeting of Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12) held on 10/11/2023 approved by the Chairperson was circulated to all members through the BIS portal as well as email vide letter no: MHD12/A2.13 dated 30/11/2023.

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 Disposal 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 product and intravascular catheters.

b) Liaison:

- 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

The Committee may please note.

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

2.3 The details of members who have not participated in the last two meetings with prior intimation are given below:

Sl. No.	Organisation	Nomination
1.	E.I. DuPont India Private Limited, Gurugram	Shri Vishnu Shankar Vyass
2.	Johnson and Johnson Private Limited, Mumbai	Ms. Himani Gupta
		Shri Hemant Sonawane

The Committee may please note.

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.

2.5 Each of the SC members are required to sign a Declaration, as prescribed by the BIS, affirming their commitment to carry out the responsibilities of a SC members with utmost sincerity. The Declaration does not have legal backing and it imposes no liability on a member. It is just an instrument of remembrance of the role and responsibilities of a TC member. Signing of the Declaration is, however, a mandatory condition for the membership of SC.

2.5.1 The details of members who have not sent the signed declaration form are given below:

S.No.	**Organization**	**Names**
1.	3M India Limited, Bengaluru	Mr. Kulveen Singh Bali
2.	Asia Pacific Medical Technology Association (APACMed), Gurugram	Ms. Shreya Bansal
3.	Association of Indian Medical Device Industry, New Delhi	Mr. Rajiv Nath
4.	B. Medical Systems India Private Limited , New Delhi	Mr. Anshuman Tuli Mr. Ketan Gayawal
5.	B. Braun Medical India Private Limited,New Delhi	Mr. Vivek Veerbhan
6.	Becton Dickinson India Private Limited, Gurugram	Mr. Nitilesh kumari Mr. Sudhakar Mairpady
7.	Boston Scientific India Private Limited, Gurugram	Mr. Prashanth Prabhakar
8.	Central Drugs Standard Control Organisation, New Delhi	Dr. Aseem Sahu Ms. Shyamni Sasidharan Mr. Pradeep
9.	E.i. Du Pont India Private Limited Gurugram	Mr.Vishnu Shankar Vyas
10.	Hindustan Syringes And Medical Devices Limited, Ballabhgarh,Faridabad	Mr. Praveen Kumar Sharma Mr. Upinder Vishen
11.	Indian Rubber Gloves Mnaufacturers Association,New Delhi	Mr. Manmohan Singh Gulati Mr. Vikas Anand
12.	Johnson And Johnson Private Limited, Mumbai	Ms. Himani Gupta Mr. Hemant Sonawane

13.	Kalam Institute Of Health Technology,Vishakhapatnam	Ms. Deepti Mr. Mohan Ragul
14.	Kanam Latex India Private Limited ,Kottayam	Mr. Donald S.K.
15.	Lady Irwin College,New Delhi	Dr. Bhawana Chanana
16.	Microtrol Sterilisation Services Private limited, Mumbai	Mr. Manoj Mishra
17.	Post Graduate Institute Of Medical Education And Research ,Chandigarh	Mr. Sanjeev Sharma Dr. Shweta Talati Dr. Navneet Dhaliwal
18.	Shriram Institute For Industrial Research , Delhi	Ms. Manish Rawat
19.	Stryker India Private Limited,Gurugram	Ms. Ishani Mondal Mr. Sanjeev Gautam
20.	Teremo Penpol Private limited, Thiruvananthapuram	Mr. V M Shajahan

The members who have not sent the signed declaration form may send the form for continuation of membership of the committee.

The committee may please note and review the composition.

2.6 Requests have been received from the following for representation on the Committee:

Sl. No.	Organisation
1.	Medtronic India Pvt Ltd, Gurugram
2.	Medical Gloves Assosiation-I&E

The committee may kindly deliberate.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 There are currently no Standards/Amendments for finalization:

The Committee may kindly note.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 There are currently no standards/amendment for the approval.

The committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 There are currently no indigenous subject drafts under preparation.

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 Comments received on the following published Indian Standards are enclosed at ***Annexure B***.

Sr No	IS Number	Title
1	IS 4148 :1989	Surgical rubber gloves – Specification

The Committee may kindly deliberate.

ITEM 7 NEW SUBJECTS

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

The Committee may kindly deliberate.

ITEM 8 TECHNICAL ISSUES

8.1 The comments received on the following documents are enclosed at ***Annexure C***.

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)
1	MHD/12/19717	Blood donor couch	17-09-2023	*Yes*
2	MHD/12/24231	Specification for Vaccine carrier - General requirements and test method	29-12-2023	*Yes*
3	MHD/12/24230	Specification for refrigerator or combined refrigerator and water pack freezer intermittent mains powered - compression cycle- general requirement and test method	29-12-2023	*Yes*
4.	MHD/12/23337	Single-use Sterile Rubber Surgical Gloves-Specification	17-10-2023	*Yes*

The Committee may kindly deliberate.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 India's Participation Status in ISO Technical Committees/Subcommittees. India is a Participating member of ISO/TC 76, ISO/TC 84 and ISO/TC 198.The membership status of India in the above ISO/TC & SC's is given below:

- ✓ ISO/TC 76 'Transfusion, infusion and injection and blood processing: (P-member) equipment for medical and pharmaceutical use'
- ✓ ISO/TC 84 'Devices for administration of medicinal product and catheters': (P-member)
- ✓ ISO/TC 198 'Sterilization of health care products' : (P-member)

9.2 List of Adopted standards as per the ISO Committee in ***Annexure D***.

The committee may kindly note.

9.3 The plenary meeting is scheduled for ISO/TC 198" Sterilization of health care products" at Ireland (Galway) on **28 Jun 2024** via Hybrid mode.

The committee may kindly note.

9.*4* The details of experts in various working groups of ISO/TC 76, ISO/TC 84 and ISO/TC 198 are given below:

a) Working groups of ISO/TC 76 :

S.No.	*Working Group*	*Title*	*Member*
1	ISO/TC 76/WG 1	Soft containers for blood, blood components and parenterals; Infusion, transfusion and blood processing equipment	Sh. Manoj A, Terumopenpol Pvt. Ltd., Thiruvananthapuram Dr. Aseem Sahu, CDSCO, New Delhi Ashok Kumar, Asian pacific Medical Technology Association, Gurugram Lt Gen Sunil Kant, Chairperson , MHD 12

			• Ms.Harshada Kadam , BIS
2	ISO/TC 76/WG 2	Rigid container systems and related accessories for parenterals and injectables	• Lt Gen Sunil Kant , Chairperson , MHD 12 • Harshada Kadam , BIS
3	ISO/TC 76/WG 4	Elastomeric parts and components and related secondary packaging components	• Dr. Aseem Sahu, CDSCO, New Delhi • Lt Gen Sunil Kant , Chairperson , MHD 12 • Ashok Kumar, Asian pacific Medical Technology Association , Gurugram • Ms. Harshada Kadam , BIS

The committee may please note.

b) Working groups of ISO/TC 84 :

S. No.	*Working Group*	*Title*	*Member*
1	ISO/TC 84/WG 3	Needle-based injection systems - Injector, container and pen needle	• Sh. Rajiv Nath, AIMED
2	ISO/TC 84/WG 8	Sharps containers	• Sh. Rajiv Nath, AIMED • Sh. P K Sharma, AIMED
3	ISO/ TC 84/ WG 10	Needles	• P. K Sharma Aimed
4	ISO/TC 84/WG 11	Syringes	• Sh. Rajiv Nath, AIMED

The committee may please note.

c) Working groups of ISO/TC 198 :

S. No.	*Working Group*	*Title*	*Member*
1	ISO/TC 198/WG 1	Industrial ethylene oxide sterilization	Sh. Bansi Dhurandhar, Microtrol Sterilisation Services Pvt. Ltd. (Mumbai) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore
2	ISO/TC 198/WG 2	Radiation sterilization	Sh. Bansi Dhurandhar , Microtrol Sterilisation Services Pvt. Ltd. (Mumbai)
3	ISO/TC 198/WG 3	Moist heat sterilization	Mr Manoj A , terumo penpol private limited
4	ISO/TC 198/WG 4	Biological indicators	Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore
5	ISO/TC 198/WG 6	Chemical indicators	Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore

6	ISO/TC 198/WG 7	Packaging	• Sh. Vishnu Vyas, Dupont, Gurgaon • Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore

The committee may please note.

9.5 Appointed Working Group Experts are obliged to inform the National Mirror Committee (i.e. the concerned BIS Technical Committee) of their contribution and progress of technical work carried out by them at the ISO level.

9.6 List of ISO Standards for adoption as Indian Standards in ***Annexure E***.

ITEM 10. PROGRAMME OF WORK

10.1 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.

10.2 Review of Indian Standards (pre-2000 Standards)

10.2.1 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.

10.2.2 As per the decision taken during the last sectional committee meeting , Panel has been created for revision/reaffirm Pre-2000 standards.

10.2.3 The Panel meeting was held on 21st Jan 2024 to review the Pre-2000 standards.

10.2.4 The minutes of the Panel meeting is placed at Annexure F.

10.2.5 The following standards have been proposed to be withdrawn as decided in the Panel Meeting .

Sr. No	IS No	Title	Scope	Recommendation	Reason
1	IS 11400 : 1985	Specification for hypodermic syringes, interchangeable type for general purposes	1.This standard covers requirements for interchangeable type, general purpose, all-glass, hypodermic syringes for medical use. 2. Unless otherwise stated in this standard, the provisions covered in IS : 3235-1980t shall apply.	To be withdrawn	• The Panel Members deliberated and found IS 11400:1985 creating duplicacy in standardization. • MHD 12 has already adopted the ISO document which is relevant to hypodermic syringes (**IS 10258**)
2	IS 1108 : 1975	Specification for pharmaceutical glass containers (Second Revision)	1. This standard prescribes the requirements, the methods of sampling and test for pharmaceutical glass containers.	To be withdrawn	• The Panel Members deliberated and found IS 1108:1975 creating duplicacy in standardization. • MHD 12 has already adopted the ISO document which is relevant to pharmaceutical glass containers(**IS/ISO 11418-1: 2016**)
3	IS 10985 : 1984	Specification for needle, acupuncture	1.Dimensional and other requirements of acupuncture needle used in acupuncture therapy.	To be withdrawn	• The Panel Members deliberated and found IS 10985:1984 standard with outdated technology , therefore panel decided to adopt the ISO standard ISO 17218:1014
4	IS 7455 : 1974	Specification for sterilizer,	1. This standard specifies requirements for	To be withdrawn	• The Panel Members deliberated and found IS 7455:1974 is fully

		pressure, hot and cold water	pressure sterilizer for hot and cold water supply in the operation theatres. The nominal capacities shall be 45 and.90 litres.		outdated and now a days this type of sterilizer is not in use .

The Committee may kindly consider.

10.3 Review of Indian Standards (as per 5-year cycle)

10.3.1 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.

10.3.2 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.

10.3.3 The list of such Indian Standards which are due for review in 2024-25 quarter is given at Annexure G.

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

ITEM 11 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

11.1 There are no specific issues.

The Committee may kindly note.

ITEM 12 STANDARD TO BE WITHDRAWN

12.1 The following standard has been identified by the BIS Secretariat for the withdrawal.

S.No.	IS No.	Title	Scope	Recommendation	Reason
1	IS 15110	Veterinary thermometers, mercury	This standard covers maximum	To be withdrawn	In line with the Minamata Convention

		- In - Glass type – Specification.	self-registering, mercury-in-glass reusable thermometers used for measuring animal body temperatures.		notification , BIS Secretariat has advised all the technical committees dealing with such products to phase out the related standards and establish alternative standards wherever required.

The committee may kindly deliberate.

ITEM 13 STANDARD FOR TRANSFER TO OTHER COMMITTEE

13.1 The following standards are identified by BIS secretarieat for transfer from MHD12 to MHD 15 as it is more relevant to the scope of MHD 15.

S.No.	IS No.	Title	Scope	Recommendation
1	IS 15113	Clinical electrical thermometers with maximum device - Specification	1.1 This standard specifies the metrological and technical requirements for clinical electrical thermometers with a maximum device. Such instruments are designed to measure human or animal body temperature. 1.2 This specification applies to battery-powered instruments which provide a digital indication of temperature	Transfer the standard from MHD 12 to MHD 15.

The committee may kindly deliberate.

ITEM 14 ANY OTHER BUSINESS

14.1 A Panel meeting was held on 31st Jan 2024 to deliberate on the comments on IS 4148: 1989, Doc MHD/12/23337 (IS 13422:1992) and IS 15354(Part 1):2023/ISO 11193(Part 1): 2020.

14.2 The Minutes of the Panel Meeting are placed in Annexure H.

14.3 Considering the decision of the panel on comments related to IS 15354(Part 1):2023 /ISO 11193 (Part 1):2020, it is proposed to introduce the following ***clause at 7.1 "The thickness of the cuff termination, measured in accordance with ISO 23529, should preferably not exceed 2.50 mm***"

The committee may kindly consider.

ITEM 15 DATE AND PLACE OF NEXT MEETING

15.1 The following dates are proposed for the meeting during 2024-25.

Quarter of FY	Q1 2024-25	Q2 2024-25	Q3 2024-25	Q4 2024-25
Month	June	September	December	March
Proposed Date	28 June, 2024 Friday	20 September, 2024 Friday	20 December, 2024 Friday	21 March, 2025 Friday

The Committee may kindly note

Annexure A

(Item No 2.2)

Composition of Sectional Committee

S.No.	Organization	Member Name	Last 3 meeting attendance
1	In Individual Capacity	Lt Gen Sunil Kant	3/3
2	3M India Limited, Bengaluru	Shri Kulveen Singh Bali	2/3
		Ms. Kavitha Kulkarni	
		Ms. Prabha Hegde	
3	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri R. Ashok Kumar	2/3
		Sh. Parveen Jain	
		Ms. Shreya Bansal	
4	Association of Indian Medical Device Industry, New Delhi	Shri Kamlesh R. Shah	2/3
		Shri Rajiv Nath	
		Shri Ravi Abraham	
5	B Medical Systems India Private Limited, New Delhi	Shri Kishor Tukaram Kaniche	0/0
		Shri. Anshuman Tuli	
		Shri. Ketan Gayawal	
6	B. Braun Medical India Private Limited, New Delhi	Shri Anmol Kumar Ray	3/3
		Shri Vivek Veerbhan	
7	Becton Dickinson India Private Limited, Gurugram	Shri Neeraj Sharma	2/3
		Shri Sudhakar Mairpady	
8	Boston Scientific India Private Limited, Gurugram	Shri Prashanth Prabhakar	3/3
		Shri Dev Chopra	
9	Central Drugs Standard Control Organization, New Delhi	Dr. Aseem Sahu	1/3
		Ms. Shyamni Sasidharan	
		Shri Pradeep	
10	E.I. DuPont India Private Limited, Gurugram	Shri. Vishnu Shankar Vyas	1/3
		Shri Srinivas S Cherukupalli	

11	ESIC Dental College and Hospital, Delhi	Dr. Mansi Atri	0/0
		Dr. Nagraj M	
		Dr Rohini Parkhiddey	
12	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	Shri Praveen Kumar Sharma	1/3
		Shri Upinder Vishen	
13	Indian Rubber Gloves Manufacturers Association , New Delhi	Shri Manmohan Singh Gulati	1/3
		Shri Vikas Anand	
		Shri Naveen Kumar Reddy	
14	Johnson and Johnson Private Limited, Mumbai	Ms. Himani Gupta	1/3
		Shri Hemant Sonawane	
15	Kalam Institute of Health Technology, Vishakhapatnam	Shri Amit Sharma	2/3
		Ms. Deepti	
		Shri Mohan Ragul	
16	Kanam Latex India Private Limited, Kottayam	Shri Donald S.K.	2/3
		Shri Abraham C. Jacob	
17	Lady Irwin College, New Delhi	Ms. Bhawana Chanana	2/3
		Ms. Sheetal Chopra	
18	Microtrol Sterilisation Services Private Limited, Mumbai	Shri Bansidhar S. Dhurandhar	1/3
		Shri Manoj Mishra	
		Shri Ranjeet V. Kalia	
19	National Institute of Health and Family Welfare, New Delhi	Mr. Hitesh Kumar	0/0
		Mr. Shivley Sageer	
20	Post Graduate Institute of Medical Education and Research, Chandigarh	Shri Sanjeev Sharma	2/3
		Ms. Shweta Talati	
		Dr. Navneet Dhaliwal	
21	Shriram Institute for Industrial Research, Delhi	Shri Manish Rawat	1/3
		Shri Sanjay Rajput	
22	Stryker India Private Limited, Gurugram	Shri Deepak Sharma	1/3
		Ms. Ishani Mondal	
		Shri Sanjeev Gautam	

23	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.	3/3
		Shri V M Shajahan	

Thanks & Regards,

Rajiv Nath
Forum Coordinator
Association of Indian Medical Device Industry (AiMeD)
901, Narain Manzil,
23, Barakhamba Road,
New Delhi – 110001
Phone : +91-129-4289065
Email :forumcoordinator@aimedindia.com
Web : www.aimedindia.com
D

From: mhd12@bis.gov.in <mhd12@bis.gov.in>
Sent: 24/01/2024 12:40 PM
To: drnavneet2008@gmail.com; hebiomed@gmail.com; naveen@vlhsglove.com; pro.delhi@rashmigroup.com; manmohan@tegamensafetyproducts.com; rohiniddey@gmail.com; deanesicglb@yahoo.com; drmansiatri@gmail.com; Pardeep <pardeep.bhar@cdsco.nic.in>; Shyamni Sasidharan <shyamni.sasidharan@cdsco.nic.in>; Shri Aseem Sahu <aseem.sahu@cdsco.nic.in>; ra@kanamlatex.com; krs@mrkhealthcare.com; forumcoordinator Aimed <forumcoordinator@aimedindia.com>
Cc: sunilkant61 <sunilkant61@gmail.com>
Subject: IS:4148 - RE-USABLE SURGICAL GLOVES IS OUT DATE

Respected Sir/Madam,

Regarding the trailing email, the Committee received the comments for IS 4148:1989 but for this standard bis have the 14 licenses . Experts may take a look on the standard and give the inputs in 31st Jan 2024 Panel meeting.

Thanking you,
Regards,
Harshada kadam
Scientist-B/Assistant Director
Medical Equipment & Hospital Planning Dept.
Bureau of Indian Standards, New Delhi

From: mhd12@bis.gov.in
To: "sunilkant61" <sunilkant61@gmail.com>
Sent: Tuesday, November 7, 2023 5:54:36 PM
Subject: Fwd: IS:4148 - RE-USABLE SURGICAL GLOVES IS OUT DATE

KL/G-011.

Annexure B
(Item 6.1)

Dear Ms. Harshada Kadam,

Sub: **IS:4148 - RE-USABLE SURGICAL GLOVES IS OUT DATE.**

We have been writing to BIS, for sometime now with regard to **validity** of present IS:4148, which is for Non-Sterile Re-usable Surgical Gloves - which requires hospitals to Sterilize the same use it and re-use it, for 5 Surgical procedures - as it's intended use. Even

CDSCO, does not recognize the concept of re-usable surgical gloves and they do not give manufacturing licence for Re-usable Surgical Gloves, with autoclave sterilization at hospital prior to use. This means:

1) Hospital purchases Non-Sterile Surgical Gloves.

2) It then autoclaves, sterilizes it and gives the product **packed in cloth** to the O.T.

3) O.T Staff and Surgeons use the gloves and then take it off and keep the used gloves and it is sent for **wash.**

4) The blood stained gloves are washed and **dried (usually hang to dry)** then powdered and again autoclaved sterilized, and used.

No one will know if the surgical glove had a **puncture** or if it's **film has lost it's barrier properties** and since the product is autoclaved sterilized without following a validated sterilization process, no one can assure that the glove is **Sterile**.

How do we still have a BIS Standard for Non-Sterile Surgical Gloves to be re-used in 2023. We just sent a space craft to the Moon.

We can have a standard for Non-Sterile Surgical Gloves for use in Wards and in ICU etc., and this is still what many hospitals still do.

Please find enclosed:

1) Our Mail dated 15th July 2022 addressed to Mr.P.Mathew (Exhibit - I).

2) Reply from Mr. P.V.Mathew dated 15/07/2022. (Exhibit II)

However, so far nothing has happened in re-validating IS:4148 and we pray that this standard is taken up without any further delay. We may be the only Country in the World that still has a National Standard for Re-usable Surgical Gloves.

This standard also has a clause for PH of gloves to be 7 $\pm$ 1. This was made when glove manufacturing was a manual process and in this process, manufacturers manually dipped moulds into acid tank and then dipped the acid coated mould into latex to coagulate the film and then further processed it. But today's process is totally different, and PH of glove is more Alkaline and hence no standard asks for gloves PH to be 7 $\pm$ 1. Why more Alkaline, because the coagulant is Alkaline and no longer Acidic.

Please do acknowledge receipt of this mail and do hope it will be taken up urgently with BIS MHD-12.

Regds,

Ravi Abraham
(Mg Director)
KANAM LATEX INDUS.PVT.LTD.
Kottayam, Kerala.

cc to: Lt.Gen.Sunil Kant(Chairperson)
cc to: Mr.Priyanka Mehra
cc to: Mr.Rajiv Nath, AIMED.
ra/ba.

Annexure C

(Item 8.1)

TITLE: BLOOD DONOR COUCH (MHD/12/19717)

NAME OF THE COMMENTATOR/ORGANIZATION: Terumo Penpol Private Limited

Sl. No.	Clause/Sub-clause/ para/table/fig. No. commented	Commentator/ Organization/ Abbreviation	Type of Comments (General/ Editorial/ Technical)	Justification	Proposed change
1	1st page,3rd para	Terumo Penpol	Technical	Any one standard should be complied, EN1041 is replaced with EN ISO 20417	Changes as below "The Standard guidelines for a user/service manual shall be in accordance with IEC/IEEE 82079-1:2019, Preparation of information for use (instructions for use) of products — Part 1: Principles and general requirements OR EN ISO 20417 standard- Information supplied by the manufacturer of medical device"
2	3/3.1	Terumo Penpol	Technical	Material should be rust free	Change 3.1 as **"**The frame body material shall be made of electric resistance butt-welded steel tube (ERW) conforming to **IS 2039**, shall be rust-free or suitable material with powder coating"
3	3/3.2		Technical	Upholstery needs to be washable and flame resistant	Change 3.2 as "Interwoven high grade leatherette as specified in **IS 577** shall be used as upholstery for the blood donor couch Or The blood donor couch shall have antimicrobial treated washable upholstery for maintaining. hygiene. The upholstery shall be resistant to liquid

					absorption. The upholstery and padding of the blood donor couch shall be flame resistant.”
4	3/3.3	Terumo Penpol	Technical	Foam needs to be flame resistant	Change 3.3 as “ non-deformable soft Polyurethane (PU) foam as per **IS 8255 or** flame-resistant foam shall be used in the blood donor couch to provide cushioned comfort to the patient”.
5	4.9	Terumo Penpol	Technical	Weighing capacity upto 135 kg is enough as overweight are not permitted for blood donation	Change 4.9 as “The blood donor couch shall be suitable for weight carrying capacity of upto 135 kg”
6	6.2.11	Terumo Penpol	Technical	Leg support can be added as optional	6.2.11 need to be made optional
7	9.3	Terumo Penpol	General	Less clarity	Change 9.3 as “BIS Certification Marking The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, Doc No: MHD 12 (19717) WC July 2023 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark, but not mandatory”
8	10 2nd sentence	Terumo Penpol	Editorial	Correction	Change Blood Collection Monitor” to “Blood Donor Couch”

TITLE : SPECIFICATION FOR VACCINE CARRIER - GENERAL REQUIREMENTS AND TEST METHOD (MHD/12/24231)

NAME OF THE COMMENTATOR: Dinesh Chugh

Sr No	Clause / Subclause No.	Comments/Suggestions along with Justification for the Proposed Change	Proposed Change/Modified Wordings
1	2. Reference	IEC 62552-1:2015 House Hold refrigerating Appliances	Not applicable as this is a passive device

TITLE: SPECIFICATION FOR REFRIGERATOR OR COMBINED REFRIGERATOR AND WATER-PACK FREEZER INTERMITTENT MAINS POWERED: COMPRESSION CYCLE, GENERAL REQUIREMENTS AND TESTING METHODS MHD/12/24230

Name of the Commentor : B Medical System Pvt Ltd

Clause No.	Original BIS Definition	Suggestive Changes by BMS India	Justification by BMS India
2	Normative references	**IEC 60335-2-24: 2020** Household and similar electrical appliances - Safety - Part 2-24: Particular requirements for refrigerating appliances, ice-cream appliances and ice-makers. **EN ISO 6270-1 / ASTM D2247 / EN 13523-26: 2014** Determination of resistance to humidity – Part 1: Continuous condensation. **EN ISO 6270-2 / EN 13523-25: 2014** Determination of resistance to humidity - Part 2: Procedure for exposing test specimens in condensation-water atmospheres **ISO 9001: 2015** Quality Management Systems – Requirements. **ISO 14001: 2015** Environmental management systems - Requirements with guidance for use. **ISO 2409: 2021** Paints and varnishes – cross cut test (external cabinet). **ISO 6272 / EN 13523-5: 2014** Impact resistance - external cabinet. **IEC 61000-6-1 edition 2.0: 2019** Electromagnetic compatibility (EMC) Generic standards - Immunity for residential, commercial and light-industrial environments. **IEC 61000-6-3** edition 2.1: 2020 Electromagnetic compatibility (EMC) Generic standards - Emission standard for residential, commercial and light-industrial environments.	Addition of additional international standards referred in Indian standards for use in conjunction with the standards already described in Normative references
3	Terms and Definitions	Add Intermittent power definition	Intermittent Power: Looking at Power infrastructure in India, specially for ruler area, The machine should perform as specified provided with 12 Hours /16 Hours of continuous power or 12 Hours /8 Hours in 24 hour day cycle. (Intermittent Power* : 12hours ON-12hours Off or 16 Hours ON-8Hours Off)
3.2	Definitions:	Hot zone should be preferred looking at the extreme climatic conditions in India to design the product that can operate at 43 deg C and its components are accordingly selected.	Although three zones are defined, but looking at Indian climate, all appliances must be designed for hot zone (43/25)

3.2.4	Overall Dimensions (Door or Lid closed):	**Below statement should be added:** To allow for maneuvering through corners, corridors and doorways, the dimension of the product (either length, width or height) should not exceed 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this will restrict the number of sites where the appliance can be installed. The maximum dimension must not exceed 1700 mm and the maximum diagonal (corner to corner) dimension must not exceed 1850 mm.	The equipment should be able to fit and pass through narrow passages and doors as can be seen in most of the ruler areas of India
3.2.5	Gross volume:	**Below statement should be added:** The measured volume of the airspace inside the internal compartment of the appliance with the door or lid shut. For combined appliances, the gross freezer volume and the gross refrigerator volume are reported separately.	The Gross volume/ capacities to be declared with the LID/Door closed of the Equipment
3.2.6	Vaccine net storage capacity	**Below statement should be added:** If a legal manufacturer would declare more than one vaccine storage capacity for the same internal and external dimensions, they must prequalify with different branding one model for each different storage volume. This capacity will be published as volume in liters.	If a manufacture declares 2 different net capacities for a same product, it should be classified into 2 different models and must attain different BIS certificate for individual models.
3.2.7	Minimum rated ambient temperature	**Below statement should be added:** The lowest constant ambient temperature at which the acceptable temperature range can be maintained with a full vaccine load. All models must be able to operate at a continuous minimum ambient temperature of +10.0°C or lower whilst maintaining the acceptable temperature range	All models must be tested to operate at a continuous minimum ambient temperature of +5.0°C to 10°C whilst maintaining the acceptable temperature range of +2°C to +8°C. This is keeping in mind the different ambient temperature ranges as per Indian geography during winters
4.2.6	Thermostat	Finally, the controller must have digital display to show set/controlled temperature values, alarm signals & facility of viewing/editing (with password protection) necessary operationalparameters. ~~Additionally, it must be equipped with buzzer element for sounding an alarm in the event of temperature breaches.~~ Buzzer must be made optional not mandatory as most of the new systems have Remote monitoring for temperatures and notify the user in case of any temperature excursion	Buzzers are not reliable for monitoring temperature excursions, Instead RTMD (Remote temperature monitoring device or EMS (Equipment monitoring system) must be in place to log and monitor any temperature excursions. We should be looking into incorporating latest technology instead relying on conventional methods
4.2.7	Thermometer	**Option C should be added:** The refrigerator compartment must be equipped with a temperature monitoring device that supports the	For better data acquisition and monitoring equipment monitoring systems must be

		transfer of data to another system for the purposes of analysis, Provision for Remote Temperature monitoring must be provided. The refrigerator manufacturer must also provide the consignee with replacement temperature monitoring devices throughout the 10-year expected lifetime of the refrigerator, so that the temperature monitoring device is always active on-site.	integrated to have a data log for all the temperature excursions for past minimum 30 days
4.2.8	Holdover time	Holdover times of refrigerators Should be categorized as follows: • Short: Holdover 24 hours ≤ 48 hours. • Medium: Holdover 48 hours ≤120 hours. • Long: Holdover 120+ hours. Note: No temperature excursion should happen below 2°C and above 8°C during the holdover period	As per the BIS draft, Hold over is mentioned as only 20 hours across all Zones, thus its of paramount importance to provide range for all zones wherein a manufacturer would want to classify their products. For Indian subcontinent as we see frequent and long power outages, specially in rural areas , hence minimum consideration for holdover should be 24 hours
4.2.9	Minimum rated ambient temperature:	Suggested to omit the line as shown : **Minimum rated ambient temperature:** All models shall be tested to establish their minimum rated ambient temperature of +10.0°C or lower whilst maintaining the acceptable temperature range. ~~The minimum acceptable performance rating is achieved if the product passesthe day/night test for its nominal temperature zone~~ The maximum performance rating is achieved if the vaccine load remains within the acceptable temperature range at -10°C. A freeze- prevention circuit may be required to protect against freezing at low ambient temperatures.	Its recommended to omit the line as it contradicts the requirements of the Minimum rated ambient temperature test.
4.2.12	Electrical safety rating:	Suggested to also add an additional computability governing EMC testing (can be added under new clause no. 4.2.13) **Electromagnetic compatibility** The legal manufacturer must certify compliance with the requirements of the latest edition of IEC 61000-6-1 and IEC 61000-6-3.	Devices must be able to work together in close environments without interference or noise compromising performance. It helps to measures how a device will react when exposed to electromagnetic noise and other disturbances. The purpose of these tests is to gain a reasonable assurance that the device will operate as intended when used within its expected operating environment.
4.3	Environmental requirements:	**Suggest Standard to be added (shown in blue)** **Environmental requirements:**	Requirements must be made mandatory for the manufacturers to ensure safe

		4.3.1 Ambient temperature range during transport and storage: -30°C to +70°C when the product is inactivated. **4.3.2 Ambient humidity range during transport, storage and use:** 5% to 95% Relative Humidity, non-condensing. **4.3.3 ISO 14001: 2015 Environmental management systems**	manufacturing practices are followers to ensure no harm occurs to Environment
4.4	Physical characteristics	**4.4.1 Overall dimensions** To allow for maneuvering through corners, corridors and doorways, the minimum dimension of the product (either length, width or height) should not exceed 710 mm; exceptionally a minimum dimension up to 830 mm can be accepted, but this will restrict the number of sites where the appliance can be installed. The maximum dimension must not exceed 1700 mm and the maximum diagonal (corner to corner) dimension must not exceed 1850 mm.	Self-explanatory
4.6.2	Materials and Finishes	**4.6.2Materials and Finishes:** All materials used inside the equipment shall not transmitodours. All materials used inside freezers **& Refrigerators** shall not contaminate vaccines stored nor transmit poisonous substances. They shall be resistant to the action of moisture. All surface finishes shall, for the purpose intended be resistant to impact, sufficiently hard, colour-fast, smooth, easily washable and resistant to damage by moisture and by acids	Refrigerator word was missing from the draft
5.1	Test 1: Cool-down, initial stabilization, and power consumption:	**Suggested changes marked in blue** **Power:Intermittent.** • **Step 1:** Set the test chamber temperature to +43°C and leave for 48 hours with the appliance empty, the lid or door open, and the power supply switched off. • **Step 2:** Close the lid or door of the appliance, commence with intermittent power**(as declared by the manufacturer) or Minimum of** ~~20 hours of continuous power followed by 4 hours with no power~~ **16 hours of continuous power followed by 8 hours with no power OR 12 hours of continuous power followed by 12 hours with no power** per 24-hour day and leave it to initially stabilize. Initial stabilization is accomplished when the appliance demonstrates all of the following:	Intermittent Power: Looking at Power infrastructure in India, specially for ruler area, The machine should perform as specified provided with 12 Hours /16 Hours of continuous power or 12 Hours /8 Hours in 24 hour day cycle. (Intermittent Power* : 12hours ON-12hours Off or 16 Hours ON-8Hours Off) (Refer Clause 3 :- Intermittent power supply definition)
5.3	Test 3: Stable running and continuous	**Suggested changes marked in blue**	Intermittent Power: Looking at Power infrastructure in India, specially for ruler area, The machine should perform

	power consumption:	**Power:** **Intermittent** • **Step 1:** Continue the Test 2 conditions but with intermittent power**(as declared by the manufacturer) or Minimum of** ~~20 hours of continuous power followed by 4 hours with no power~~ **16 hours of continuous power followed by 8 hours with no power OR 12 hours of continuous power followed by 12 hours with no power** per 24-hour day and the same temperature monitoring regime, but cycle the power supply intermittently until the temperature has re-stabilized and a minimum of three repeating 24-hour temperature profile cycles have been completed3.	as specified provided with 12 Hours /16 Hours of continuous power or 12 Hours /8 Hours in 24 hour day cycle. (Intermittent Power* : 12hours ON-12hours Off or 16 Hours ON-8Hours Off) (Refer Clause 3 :- Intermittent power supply definition)
5.5	Test 5: Holdover time test	**Suggested changes marked in blue** **Acceptance criterion:** ~~A minimum of 4 hours at a continuous ambient temperature of +43°C.~~ **Acceptance criterion ILRs should be able to provide holdover (To maintain temperatures in desired range, 2℃ to 8℃) for ≥ 24 hours. No temperature excursion should happen below 2℃ and above 8℃**	As per initial draft 4 hour holdover acceptance criteria defies all odd of having an ILR, the minimum acceptance should be at least 24 hours as foreseeing the electricity outages in India. The ILR should be able to maintain temperatures inside of vaccine storage cabinet in range of 2 deg C to 8 Deg C for atleast 24 hours after the power supply is cut off
5.8	Test 8: Day/night test	**Suggested changes marked in blue** ~~**Step 2:** Switch the appliance on, initially with continuous power, and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -3°C. Allow to run fora further 24 hrs~~. **Step 2: Stabilize the appliance, initially with Intermittent power, and stabilize the vaccine load temperature between +2°C and +8°C and the water-pack freezing compartment (if present) below -3°C. Allow stabilization at Intermittent power for atleast 48 Hours**	Intermittent power should be used for initial stabilization and continuous power should not be used (as was described in initial draft of BIS), as all intermittent power testes are to be performed with Intermittent power profile
5.8	Test 8: Day/night test	**Suggested changes marked in blue**	For corrected distribution of solar day cycle, the machine

		~~**Step 3:** Start the intermittent power cycle by disconnecting the power for the next 16 hours. Simultaneously begin the day/night cycle by reducing the temperature of the test chamber to M: +10ºC, T: +15ºC, H: +25ºCover a3 hour period. Hold this temperature for 9 hours. Raise the temperature toM: +27ºC, T: +32°C, H: +43°C over a 3 hour period. Hold at M: +27ºC, T: +32°C, H: +43°C for a further 9 hours. Reduce again to M: +10ºC,T: +15ºC, H: +25ºC again over a further 3 hr period. Repeat this simulated day/night temperature and 16 hour power off, eight hour power on cycle five times. Record the vaccine load temperature every minute.~~ **Step 3: Once the Dummy load are stabilized at Intermittent power, Commence with the start of the intermittent power phase begin with a 12 hour day phase of a 24 hour solar cycle hold the temperature of the test chamber to M:+27ºC, T:+32°C, H:+43°C, for a further 12 hours. Then lower the temperature to M:+10ºC, T:+15ºC, H:+25ºC over a 3 hour period. Hold at M:+10ºC, T:+15ºC, H:+25ºC for a further 9 hours. Next raise the ambient temperature to M:+27ºC, T:+32°C, H:+43°C over a further 3 hour period. Hold at M:+27ºC, T:+32ºC, H:+43ºC for a further 9 hours. Repeat this simulated day-night cycle for five complete 24-hour cycles in total**	is allowed to operate for initial 12 hours (on intermittent power cycle), followed by lowing the ambient (test room) temperature to 25 degrees over the period of 3 hours, and then holding the ambient (test room) temperature of next 9 hours at 25 degrees, and then raising the ambient (testroom temperature) to 43 deg C over the period of 3 hours and holding at 43 deg C for next 9 hours, Thus completing the Solar cycle to replicate the day and night conditions. This has to be done for 5 cycles in total.
7	Marking and Information	**Suggested addition to this clause : Compressors must be marked with the blue identifying symbol. In addition, the cabinet must be permanently marked, near the compressor position, with the chemical name of the refrigerant or with the refrigerant number, formula or proportion (for blended refrigerants). Appliances operating on R600a must be marked with the warning symbols**	Point self explanatory
10	Disposal and recycling	**Suggested addition to this clause :**	As part of extended producer responsibility and to use the E waste disposal symbol on the labels it is mandatory

			The legal manufacturer must provide information to the buyer on the hazardous materials contained within the system and suggestions for resource recovery/recycling and/or environmentally safe disposal. For legal manufacturers from the India, CEEW2/LSEEW2/LIW2 compliance in accordance with E-Waste (Management) Rules 2022] Directive is mandatory	comply to E-waste management rules 2022

-------- Forwarded Message --------
Subject: Request to Update BIS Standard IS 13422 for Surgical Gloves
Date: Sat, 5 Aug 2023 17:08:15 +0530
From: Kanam Latex Ind Pvt Ltd <ho@kanamlatex.com>
To:mhd12@bis.gov.in
CC: Donald S . K. <donaldsk@kanamlatex.com>, Ank-Varghese <tcvarghese@kanamlatex.com>, Ravi R <ravir@kanamlatex.com>

KL/G-11.

Annexure C

Dear Mr.Harshada Kadam,

This has reference to your mail dated 26th July for Surgical gloves.

IS:13422 was a standard developed when Surgical glove was considered as Rubber Glove and not a Medical Device. Today, Surgical Glove is not a Rubber Glove, but considered as **Medical Device** and this is captured more in the updated ISO 10282-23 standards, which addresses many of the deficiencies in IS 13422. However there are few changes that we, in India, should make to our National Standards and not copy ISO 10282-23 and they are:

1) Clause 7.1 Table 2: Glove length.

The glove length for Size 6-9 should be minimum 280mm. In case of size 5 & 5.5-it can be 265mm or 280mm.

Minimum thickness and location for measurements:

ISO 10282 suggests thickness of 0.10mm for smooth area and 0.13mm for thickness in area which glove is textured. We suggest a minimum thickness of 0.13mm irrespective of finish on the glove. What is important is Force at Break in Newton and not glove thickness. Thinner the glove-less the force at break. In fact EN 455 has recognized this and they have only specified **Force at break** which has a direct relationship to glove thickness and film formation.

One glove will have different surface finish. It can be smooth from beading to wrist and then **textured in inner finger and palm and smooth on outer palm and fingers.** Textures are many type-it can be Micro textures (which many refer to as smooth) or it can be textured surface when made and can be subsequently treated to make a smooth (for example-application of polymer or chlorination).

Texture can be Micro/Macro and Rough and in between and there is no scientific basis for giving an increase of 0.03mm for texture.

In fact no other International or National standard other than ISO 10282 have this clause. This may be deleted.

2) Clause 6.1-Table of inspection and AQL.

The primary requirement of Surgical glove is use for surgery and hence barrier properties in extremely important. ISO 10282 prescribes AQL of 1.5, which is too lenient for intended purpose. Hence like EN 455-We suggest AQL of 0.65 or at least AQL 1 and not relaxed AQL of 1.5.

3) 7.3.1 specifies that Test piece for dumb -bell cut piece should be taken from Palm or back of the Palm.

We suggest that Dumb bell cut piece should be taken from area that is smooth (if available) and not from area like Palm-which could have textured and outer palm which could be smooth and more over - most manufacturers have size of glove embossed on back side of the hand and this will distort the actual glove strength. The ideal location is the area from Wrist to cuff. More over this is the area that is subject to most stress as the Surgeon when donning gloves pulls this area to put glove on to his hand. Hence the area from wrist to cuff is the ideal place to take dumb bell cut piece.

4) 9.3 clause C&D:

The words Textured/Smooth, Straight/curved should be deleted as Mandatory requirement. They do not effect the efficacy of the product and the choice to label primary pack is uncalled for. It should be left to the discretion of the manufacturer and buyer. Mandatory labelling must address important aspects and not everything.

5) Allergens:

ISO 10282 is silent on Allergen. Water extractable latex protein is known to be cause Type-1 allergy and hence standard we adopt must mention both Latex Allergen and it's test method.
Both EN and ASTM have specified Test method for measuring Allergen and our National Standard must address this aspect.

Suggest that water extractable Natural rubber protein should not exceed 150ug/g.

Regards,

Ravi Abraham
(Mg.Director)
KANAM LATEX INDUS.PVT.LTD.
Ooppoottil Buildings, K.K. Road
Kottayam, Kerala.

Encls: We are enclosing the changes needed in ISO:10282-23.

cc to: Mr.Donald/Mr.T.C.Varghese/Mr.Ravi R

ra/ba.

-------- Forwarded Message --------
Subject: Request to Update BIS Standard IS 13422 for Surgical Gloves
Date: Wed, 26 Jul 2023 21:52:47 +0530 (IST)
From: mhd12@bis.gov.in
To: abhay@disposafe.com, adeokar@midmark.com, ANILKUMAR TEOTIA <akteotia.ipc@gov.in>, anair25@ITS.JNJ.com, anil.teotia@gmail.com, Dr Anurag Mishra <anurag.mishra@gov.in>, avats@ITS.JNJ.com, avsrkp1768@yahoo.co.in, bansi@microtrol-india.com, bhawanachanana@gmail.com, Priya Nair <dd2tpd-doc@nic.in>, deepak@nat-steel.com, deepakghuliani@hotmail.com, dratulirms@yahoo.com, drnavneet2008@gmail.com, drvkmonga@yahoo.com, executivedirector@kiht.in, ho@kanamlatex.com, hsg@ima-india.org, info@hmdhealthcare.com, info@medivalley-aic.in, info@pricon.co.in, jayant@nat-steel.com, jbera@iitk.ac.in, joshid@iitd.ac.in, Kanwalinder Singh Sodhi <kanwalinder.sodhi@nic.in>, manoj.g@kiht.in, manoj@microtrol-india.com, MANOJ KUMAR <mkpandey.ipc@gov.in>, np@ima-india.org, peic@roltanet.com,

Annexure D

(*Item No 9.2)*

ISO STANDARDS PUBLISHED UNDER ISO/TC 76
Standard 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.	Title	Status	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
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
3.	ISO 1135-3:2016	Transfusion equipment for medical use — Part 3: Blood-taking sets for single use	Adopted	IS 1135-3 : 2016
4.	ISO 1135-4:2015	Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed	Adopted	IS 1135-4 : 2015
5.	ISO 1135-5:2015	Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus	Docs in Print	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 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	Docs in development	MHD/12/23259

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 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 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 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	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	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
15.	ISO 6717:2021	In vitro diagnostic medical devices — Single use containers for the collection of specimens from humans other than blood	Docs in development	MHD/12/23591
16.	ISO 8362-1:2018	Injection containers and accessories — Part 1: Injection vials made of glass tubing	Adopted	IS 1984 (Part 1) : 2023
17.	ISO 8362-2:2015	Injection containers and accessories — Part 2: Closures for injection vials	Adopted	IS 1984 (Part 4) : 2023
18.	ISO 8362-2:2015/Amd 1:2022	Injection containers and accessories — Part 2: Closures for injection vials — Amendment 1	Not Adopted	
19.	ISO 8362-3:2001	Injection containers and accessories — Part 3: Aluminium caps for injection vials	Adopted	IS 1984 (Part 3) : 2023
20.	ISO 8362-4:2011	Injection containers and accessories — Part 4: Injection vials made of moulded glass	Adopted	IS 1984 (Part 2) : 2023
21.	ISO 8362-5:2016	Injection containers and accessories — Part 5: Freeze drying closures for injection vials	Docs in development	MHD/12/23650
22.	ISO 8362-6:2010	Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials	Docs in development	MHD/12/23652
23.	ISO 8362-7:2006	Injection containers and accessories — Part 7: Injection caps made of aluminium-	Not Adopted	

		plastics combinations without overlapping plastics part		
24.	ISO 8536-1:2011	Infusion equipment for medical use — Part 1: Infusion glass bottles	Adopted	IS 8536-1 : 2011
25.	ISO 8536-2:2023	Infusion equipment for medical use — Part 2: Closures for infusion bottles	Not Adopted	
26.	ISO 8536-3:2009	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles	Not Adopted	
27.	ISO 8536-3:2009/Amd 1:2022	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles — Amendment 1	Not Adopted	
28.	ISO 8536-4:2019	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed	Adopted	IS 8536-4 : 2019
29.	ISO 8536-5:2004	Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed	Not Adopted	
30.	ISO 8536-6:2016	Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles	Not Adopted	
31.	ISO 8536-7:2009	Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles	Not Adopted	
32.	ISO 8536-8:2015	Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus	Not Adopted	
33.	ISO 8536-9:2015	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment	Not Adopted	
34.	ISO 8536-10:2015	Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment	Not Adopted	
35.	ISO 8536-11:2015	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment	Not Adopted	
36.	ISO 8536-12:2021	Infusion equipment for medical use — Part 12: Check valves for single use	Not Adopted	
37.	ISO 8536-13:2016	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact	Not Adopted	
38.	ISO 8536-14:2016	Infusion equipment for medical use — Part 14: Clamps and flow regulators for	Not Adopted	

		transfusion and infusion equipment without fluid contact		
39.	ISO 8536-15:2022	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use	Not Adopted	
40.	ISO 8536-15:2022/Amd 1:2023	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use — Amendment 1	Not Adopted	
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 — General requirements and test methods	Not adopted	
48.	ISO 9187-1:2010	Injection equipment for medical use — Part 1: Ampoules for injectables	Adopted	IS 15537 : 2021
49.	ISO 9187-2:2010	Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules	Adopted	IS 15537 (Part 2) : 2023
50.	ISO 11040-1:2015	Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges	Adopted	IS 11040 (Part 1) : 2015
51.	ISO 11040-2:2011	Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges	Adopted	IS 11040-2 : 2011
52.	ISO 11040-3:2012	Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges	Adopted	IS 11040-3 : 2012

53.	ISO 11040-4:2015	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Adopted	IS 11040-4 : 2015
54.	ISO 11040-4:2015/Amd 1:2020	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling — Amendment 1	Docs in Print	MHD/12/23261
55.	ISO 11040-5:2012	Prefilled syringes — Part 5: Plunger stoppers for injectables	Adopted	IS 11040-5 : 2012
56.	ISO 11040-6:2019	Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Not adopted	
57.	ISO 11040-7:2015	Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling	Not adopted	
58.	ISO 11040-8:2016	Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes	Not adopted	
59.	ISO 11418-1:2016	Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing glass bottles	Adopted	IS 11418-1 : 2016
60.	ISO 11418-2:2016	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups	Adopted	IS 11418-2 : 2016
61.	ISO 11418-2:2016/Amd 1:2017	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups — Amendment 1	Not adopted	
62.	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 11418-3 : 2016
63.	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	Not adopted	
64.	ISO 11418-4:2005	Containers and accessories for pharmaceutical preparations — Part 4: Tablet glass bottles	Not adopted	
65.	ISO 11418-5:2015	Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies	Adopted	IS 11418-5 : 2015

66.	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 11418-7 : 2016
67.	ISO 13926-1:2018	Pen systems — Part 1: Glass cylinders for pen-injectors for medical use	Adopted	IS 13926-1 : 2018
68.	ISO 13926-2:2017	Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use	Adopted	IS 13926-2 : 2017
69.	ISO 13926-3:2019	Pen systems — Part 3: Seals for pen-injectors for medical use	Adopted	IS 18293 (Part 3) : 2023
70.	ISO 15010:1998	Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods	Not adopted	
71.	ISO 15137:2005	Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods	Not adopted	
72.	ISO 15375:2010	Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods	Not adopted	
73.	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 15378 : 2017
74.	ISO 15747:2018	Plastic containers for intravenous injections	Docs in development	MHD/12/23655
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	Not adopted	
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	Not adopted	
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	Not adopted	

ISO/TC 198

ISO STANDARDS PUBLISHED UNDER ISO/TC 198

Standard published under ISO/TC 198

Sterilization of health care products

Scope:

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

S.NO.	IS/ISO	Title	Status	IS/Doc. No.
1.	ISO/TS 5111:2022	Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products	Docs in print	MHD/12/23990
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 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 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	IS 11137-1 : 2006
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	Docs in development	MHD/12/22910

7.	ISO 11137-2:2013	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	Adopted	IS 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	Docs in print	MHD/12/23262
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 11137-3 : 2017
10.	ISO/TS 11137-4:2020	Sterilization of health care products — Radiation — Part 4: Guidance on process control	Not adopted	
11.	ISO 11138-1:2017	Sterilization of health care products — Biological indicators — Part 1: General requirements	Adopted	IS 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 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 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 11138-4 : 2017
15.	ISO 11138-5:2017	Sterilization of health care products — Biological indicators — Part 5: Biological indicators for lowtemperature steam and formaldehyde sterilization processes	Adopted	IS 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
17.	ISO 11138-8:2021	Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced	Adopted	IS 18469 (Part 8) : 2023

		incubation time for a biological indicator		
18.	ISO 11139:2018	Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards	Adopted	IS 18240 (Part 89) : 2023
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 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	Not 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 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 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	Docs in development	MHD/12/23986

26.	ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems	Adopted	IS 11607 : 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 : 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 11737-1 : 2018
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	Docs in print	MHD/12/23263
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 11737-2 : 2019
33.	ISO 11737-3:2023	Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing	Not adopted	
34.	ISO 13004:2022	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	Not adopted	

35.	ISO 13408-1:2023	Aseptic processing of health care products — Part 1: General requirements	Adopted	IS 13408-1 : 2008 ISO 13408-1:2008
36.	ISO 13408-2:2018	Aseptic processing of health care products — Part 2: Sterilizing filtration	Adopted	IS 13408-2 : 2018
37.	ISO 13408-3:2006	Aseptic processing of health care products — Part 3: Lyophilization	Not adopted	
38.	ISO 13408-4:2005	Aseptic processing of health care products — Part 4: Clean-in-place technologies	Not adopted	
39.	ISO 13408-5:2006	Aseptic processing of health care products — Part 5: Sterilization in place	Not adopted	
40.	ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems	Not adopted	
41.	ISO 13408-7:2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products	Not adopted	
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	Docs in development	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 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 15883-1 : 2006

46.	ISO 15883-1:2006/Amd 1:2014	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests — Amendment 1	Not adopted	
47.	ISO 15883-2:2006	Washer-disinfectors — Part 2: Requirements and tests for washerdisinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	Adopted	IS 15883-2 : 2006
48.	ISO 15883-3:2006	Washer-disinfectors — Part 3: Requirements and tests for washerdisinfectors employing thermal disinfection for human waste containers	Adopted	IS 15883-3 : 2006
49.	ISO 15883-4:2018	Washer-disinfectors — Part 4: Requirements and tests for washerdisinfectors employing chemical disinfection for thermolabile endoscopes	Adopted	IS 18344 (Part 4) : 2023
50.	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	Docs in print	MHD/12/20837
51.	ISO 15883-6:2011	Washer-disinfectors — Part 6: Requirements and tests for washerdisinfectors employing thermal disinfection for non-invasive, noncritical medical devices and healthcare equipment	Adopted	IS 15883-6 : 2011
52.	ISO 15883-7:2016	Washer-disinfectors — Part 7: Requirements and tests for washerdisinfectors employing chemical disinfection for non-invasive, noncritical 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

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	Docs in print	MHD/12/20835
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	Docs in print	MHD/12/20832
56.	ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Adopted	IS 18319 (Part 1) : 2023
57.	ISO/TS 17665-2:2009	Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1	Not adopted	
58.	ISO/TS 17665-3:2013	Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization	Not adopted	
59.	ISO 18362:2016	Manufacture of cell-based health care products — Control of microbial risks during processing	Not adopted	
60.	ISO 18362:2016/Amd 1:2022	Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1	Not adopted	
61.	ISO 18472:2018	Sterilization of health care products — Biological and chemical indicators — Test equipment	Not adopted	
62.	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

63.	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	
64.	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
65.	ISO/TS 22421:2021	Sterilization of health care products — Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities	Not adopted	
66.	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	
67.	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	
68.	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	
69.	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	

ISO/ TC 84

ISO STANDARDS PUBLISHED UNDER ISO/TC 84
Standard 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	**IS/ISO**	**Title**	**Status**	IS/Doc. No.
1.	ISO 6009:2016	Hypodermic needles for single use — Colour coding for identification	Adopted	IS 16004 : 2013 ISO 6009: 1992
2.	ISO 7864:2016	Sterile hypodermic needles for single use — Requirements and test methods	Adopted	IS 10654 : 2018
3.	ISO 7886-1:2017	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use	Adopted	IS 10258 : 2002
4.	ISO 7886-2:2020	Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps	Docs in development	MHD/12/20820
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
6.	ISO 7886-4:2018	Sterile hypodermic syringes for single use — Part 4: Syringes with re-use prevention feature	Not adopted	
7.	ISO 8537:2016	Sterile single-use syringes, with or without needle, for insulin	Adopted	IS 12227 : 2020
8.	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods	Not adopted	
9.	ISO 10555-1:2023	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements	Adopted	IS/ISO 10555-1 : 2013 ISO 10555-1 : 2013
10	ISO 10555-3:2013	Intravascular catheters — Sterile and singleuse catheters — Part 3: Central venous catheters	Adopted	IS 10555-3 : 2013

11	ISO 10555-4:2023	Intravascular catheters — Sterile and singleuse catheters — Part 4: Balloon dilatation catheters	Adopted	IS/ISO 10555-4 : 2013
12	ISO 10555-5:2013	Intravascular catheters — Sterile and singleuse catheters — Part 5: Over-needle peripheral catheters	Adopted	IS 10555-5 : 2013
13	ISO 10555-6:2015	Intravascular catheters — Sterile and singleuse catheters — Part 6: Subcutaneous implanted ports	Docs in development	MHD/12/23904
14	ISO 10555-6:2015/Amd 1:2019	Intravascular catheters — Sterile and singleuse catheters — Part 6: Subcutaneous implanted ports — Amendment 1	Not adopted	
15	ISO 10555-7:2023	Intravascular catheters — Sterile and single-use catheters — Part 7: Peripherally inserted central catheters	Not Adopted	
16	ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires	Docs in print	MHD/12/19187
17	ISO 11070:2014/Amd 1:2018	Sterile single-use intravascular introducers, dilators and guidewires — Amendment 1	Not 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	Not adopted	
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 overneedle 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	Docs in development	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
31	ISO 20697:2018	Sterile drainage catheters and accessory devices for single use	Adopted	IS 18451 : 2023
32	ISO 20698:2018	Catheter systems for neuraxial application — Sterile and single-use catheters and accessories	Docs in print	MHD/12/19191
33	ISO 21649:2023	Needle-free injection systems for medical use — Requirements and test methods	Not adopted	
34	ISO 23907-1:2019	Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers	Docs in print	MHD/21/13433
35	ISO 23907-2:2019	Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers	Not adopted	
36	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	Docs in print	MHD/21/22114

Annexure E

(Item 9.6)

List of ISO Standards to be adopted as a Indian Standards :

S.No.	ISO	Title
1.	ISO/TS 23128:2019	Medical devices — Transfusion set and blood bag compatibility test method
2.	ISO 21881:2019	Sterile packaged ready for filling glass cartridges
3.	ISO 28620:2020	Medical devices — non-electrically driven portable infusion devices
4.	ISO/TS 11137-4:2020	Sterilization of health care products — Radiation — Part 4: Guidance on process control
5.	ISO 11737-3:2023	Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing
6.	ISO 13004:2022	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD
7.	ISO 9626:2016	Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods
8.	ISO 10555-1:2023	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements
9.	ISO 10555-4:2023	Intravascular catheters — Sterile and single use catheters — Part 4: Balloon dilatation catheters
10.	ISO 10555-7:2023	Intravascular catheters — Sterile and single-use catheters — Part 7: Peripherally inserted central catheters
11.	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

Annexure F

(Item 10.2.4)

Minutes of 2nd panel meeting

Sr. No.	IS Number	Title	Remarks
1.	IS 11400 : 1985	Specification for hypodermic syringes, interchangeable type for general purposes	Panel has decide to withdraw this standard.
2.	IS 1108 : 1975	Specification for pharmaceutical glass containers	Panel has decide to withdraw this standard.
3.	IS 11043 : 1984	Specification for needle, epidural	The panel determines that modifications are necessary for this standard.
4.	IS 10985 : 1984	Specification for needle, acupuncture	Panel has decide to withdraw this standard.
5.	IS 10603 : 1983	Specification for abdominal belts	Panel has decide to reaffirm this standard.
6.	IS 12173 : 1987	Specification for cervical halter	The panel decided to seek the opinion of the sectional committee on this standard.
7.	IS 3236 : 1992	Hypodermic syringes for general purposes – Specification	The panel has decided to seek reconfirmation from Mr. Sudhakar Mairpady,BDIPL Gurugram.
8.	IS 3237 (Part 1) : 1985	Specification for special purpose syringes: Part 1 insulin syringes	The panel has chosen to circulate the standard among manufacturers and gather their opinions.
9.	IS 3237 (Part 2) : 1985	Specification for special purpose syringes: Part 2 tuberculin syringes	The panel has chosen to circulate the standard among manufacturers and gather their opinions.
10.	IS 13115 : 1991	Portable first - Aid kit for general use - Specification	The panel has opted to request input from

			manufacturers and then proceed with revisions accordingly.
11.	IS 3118 : 1978	Specification for electric bacteriological incubators (First Revision)	The panel has decided to reach out to manufacturers and user, gather their inputs and opinions.
12.	IS 3119 : 1978	Specification for hot air sterilizers	The panel has decided to reach out to manufacturers and gather their inputs and opinions.
13.	IS 3120 : 1999	Baby incubators - Specification (Second Revision)	The panel has decided to revise this standard.
14.	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)	The panel has decided to review this standard.
15.	IS 3829 (part 2) : 1978	Specification for steam sterilizers: Part 2 horizontal cylindrical high speed steam sterilizers, pressure type (First Revision)	The panel has decided to review this standard.
16.	IS 3829 (part 3) : 1985	Specification for steam sterilizers: Part 3 pressure sterilizers, vertical cylindrical type	The panel has decided to review this standard.
17.	IS 3831 : 1979	Specification for sterilizer, shallow (Dressing Drum)	The panel has decided to revise this standard.
18.	IS 5022 : 1989	Sterilizer, instruments, table model (Third Revision)	The panel has decided to revise this standard.
19.	IS 5035 : 1969	Specification for sterilizers, bowl and utensil (Pedal Type)	The panel has decided to revise this standard.
20.	IS 5630 : 1994	Cribs (Cradles), maternity - Specification (First Revision)	The panel has decided to seek input inputs from Gynecology and obstetrics dept.

21.	IS 6877 : 1977 ISO 20795-1 : 2013	Specification for cabinet, instruments (First Revision)	Panel has decide to reaffirm this standard.
22.	IS 6905 : 1973	Instruments Table, Mayo's Type	The panel has decided to seek inputs from Ms. Dr. Navneet Dhaliwal, PGIMER Chandigarh.
23.	IS 7350 : 1974	Specification for needles, spinal	The panel has decided to seek inputs from Mr. Sudhakar Mairpady, BDIPL Gurugram.
24.	IS 7387 : 1974	Needle, Biopsy, Liver, Silverman's Pattern	The panel has decided to seek inputs from Mr. Sudhakar Mairpady, BDIPL Gurugram.
25.	IS 7455 : 1974	Specification for sterilizer, pressure, hot and cold water	Panel has decide to withdraw this standard.
26.	IS 7523 : 1974	Specification for rubber catheter (Urinary)	The panel has decided to revise this standard.

Annexure G

(Item No 10.3.3)

S.No.	IS Number	IS Title	Due Date
1.	IS 12227 : 2020 ISO 8537 : 2016	Sterile Single-Use Syringes, With or Without Needle, for Insulin (Second Revision)	March, 2025
2.	IS 3120 : 1999	Baby incubators - Specification (Second Revision)	April, 2024
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
4.	IS 3993 : 1993	Trays, instruments - Specification (Second Revision)	December, 2024
5.	IS 3994 : 1993	Bowls,wash - Specification (Second Revision)	December, 2024
6.	IS 5022 : 1989	Sterilizer, instruments, table model (Third Revision)	May, 2024
7.	IS 5630 : 1994	Cribs (Cradles), maternity - Specification (First Revision)	April, 2024
8.	IS/ISO 10555-4 : 2013	Sterile, single - Use intravascular catheters: Part 4 balloon dilatation catheters	December, 2024

Annexure H

(Item 14.2)

ITEM 1 DISCUSSION POINTS

1.1 The Panel deliberated on the comments on IS 4148:1989 and decided to get inputs from all licensees within a period of 15 days. The received inputs will be taken up at the next Panel meeting for further discussion.

1.2 The Panel deliberated on the comments on Doc: MHD/12/23337 (IS 13422:1992) and decided to get inputs from all licensees within the period of 15 days. The received inputs will be taken up at the next Panel meeting for further discussion.

1.3 The Panel deliberated and decided to consider the comment for IS 15354(Part 1): 2023. In the next sectional committee meeting final decision will be taken regarding the acceptance of the comments.