**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 ) | 13 | 10 Nov 2023 04:00 pm |
| ***via Webex platform***<br>**Meeting Link**:https://bismanak.webex.com/bismanak/j.php?MTID=m96a1cc1e97b43742fc87dfb7b02bb358<br>**Meeting Number**: 2510 595 6613<br>**Password**:Mhd@12 | | |
| **Chairperson**<br>**Lt Gen Sunil Kant** | **Member Secretary**<br>**MsHarshada Ganesh Kadam** | |

**ITEM 0 GENERAL**

**0.1 WELCOME ADDRESSES BY MEMBER SECRETARY**

**0.2 OPENING REMARKS BY CHAIRPERSON**

**ITEM 1CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING**

1.1 The minutes of the 12thmeeting of Hospital Equipment and Surgical Disposable Products Sectional Committee (MHD 12)held on 04/09/2023approved by the Chairperson was circulated to all members through the BIS portalas well as email vide letter no: MHD12/A2.12 dated 08/09/2023.

1.2 No comments have been received so far.

*The Committee may formally confirm the minutes.*

**ITEM 2SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE**

2.1The present scope of Hospital Equipment and Surgical DisposalSectional Committee (MHD 12)is as follows:

a) To formulate Indian Standards for:

i) Hospital equipment used in OPD wards and operation theaters such as Sterilizers, Incubators,

hospital furniture, and operation tables etc.

ii) 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 MHD 12 is given in **ANNEX 1.** The Committee may note and review its composition according to following BIS guidelines, keeping reasonable and manageable number of members on the committee.

- Consumer interests shall, as far as possible, predominate. In case non industry interests are less than two third, it may be reviewed to ensure that $2/3_{rd}$ of the total representation on the committee is from non-industry.
- Only relevant organizations/ government departments/ consumer organizations/ regulatory bodies that are related to the subject may be offered representation.
- Non-active members to be withdrawn and young professionals who can contribute in the working of the committee may be co-opted. The committee may deliberate on the same and advise.

*The Committee may please note*.

2.3 Members are also requested to provide their latest details like e-mail, phone no, enabling secretariat to make correspondence and send documents/Agenda/Minutes etc. through e-mail.

2.4Co-option received

| Sl. No. | Organisation | Nomination |
|---|---|---|
| 1. | B Medical Systems Pvt Ltd | Mr Sameer Sayeed |
| 2. | Medical Technology Association Of India | Mr. Nadeem ParvezAnam |

2.5 The Following experts are identified by BIS secretarieat :

| SI.No | Organization | Experts |
|---|---|---|
| 1 | National Institute of Health & Family Welfare | Mr. Shivley Sageer<br>Mr.Hitesh Kumar<br>Mr.Anjaney shahi |

## ITEM 3 DRAFT INDIAN STANDARDS UNDER PRINT

As per the decision of the last meeting, the following mentioned documents were sent to publication.

| SI. No. | Doc No | TITLE |
|---|---|---|
| 1. | MHD 12 (20816) | Injection containers and accessories Part 4: Closures for injection vials |
| **2.** | MHD 12 (19190) | Sterile drainage catheters and accessory devices for single use |
| 3. | MHD 12 (20835) | 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 |
| 4. | MHD 12 (20826) | Sterilization of health care products Biological indicators Part 8: Method for validation of a reduced incubation time for a biological indicator |
| 5. | MHD 12 (20828) | Sterilization of health care products Chemical indicators Part 1: General requirements |
| 6. | MHD 12 (17339) | Transfusion equipment for medical use Part 5 Transfusion sets for single use with pressure infusion apparatus |
| 7. | MHD 12 (20837) | Washer-disinfectors Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy |
| 8. | MHD 12 (19191) | Catheter systems for neuraxial application Sterile and single-use catheters and accessories |
| 9. | MHD 12 (20832) | 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 |
| 10. | MHD 12 (16286) | Pen systems Part 3 Seals for pen-injectors for medical use |
| 11. | MHD 12 (18070) | Sterilization of health care products Moist heat Part 1 Requirements for the development validation and routine control of a sterilization process for medical devices |
| 12. | MHD 12 (20819) | Injection equipment for medical use Part 2 One-point-cut OPC ampoules |
| 13. | MHD 12 (20825) | Sterilization of health care products Biological indicators Part 7: Guidance for the selection use and interpretation of results |

*The committee may please note.*

**ITEM 4DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION**

4.1 The following draft Indian Standards / Amendments have been sent for wide circulation:

| Sl. No. | Document No. | Title | Last date for comments | Comments received (Yes/No) |
|---|---|---|---|---|
| 1. | MHD 12 (23259) | Plastics collapsible containers for human blood and blood components Part 1 Conventional containers First Revision Amendment - 1 | 17-08-2023 | No |
| 2. | MHD 12 (23890) | 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 Part 1: Critical and semi-critical medical devices | 20-10-2023 | No |
| 3. | MHD 12 (19717) | Blood Donor Couch Specification | 17-08-2023 | No |
| 4. | MHD/12/23650 | Injection Containers and Accessories Part 5: Freeze Drying Closures for Injection Vials | 03-10-2023 | No |
| 5. | MHD/12/23262 | Sterilization of health care products - Radiation: Part 2 establishing the sterilization dose Amendment - 1 | 17-08-2023 | No |
| 6. | MHD/12/23907 | 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 | 20-10-2023 | No |
| 7. | MHD/12/22897 | Specification for Filter and Filter Chamber for Blood Transfusion | 18-07-2023 | No |
| 8. | MHD/12/18073 | STERILIZER PORTABLE VERTICAL PRESSURE TYPE SPECIFICATION First Revision | 27-10-2023 | No |
| 9. | MHD/12/23655 | Plastic Containers for Intravenous Injections | 03-10-2023 | No |
| 10. | MHD/12/23587 | Injection containers and accessories Part 5: Freeze drying closures for injection vials | 20-09-2023 | No |
| 11. | MHD/12/23260 | Intravascular catheters - Sterile and single - Use catheters: Part 1 general requirements (First Revision) Amendment - 1 | 03-10-2023 | No |
| 12. | MHD/12/23900 | Guidance for assessment and evaluation of changes to drug delivery systems | 20-10-2023 | No |
| 13. | MHD/12/19718 | Dialysis Chair | 03-10-2023 | No |
| 14. | MHD/12/23652 | Injection Containers and Accessories Part 6: Caps Made of Aluminium-Plastics Combinations for Injection Vials | 19-10-2023 | No |
| 15. | MHD/12/23263 | Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products Amendment - 1 | 17-08-2023 | No |

| | | | | |
|---|---|---|---|---|
| 16. | MHD/12/22910 | Sterilization of health care products - Radiation: Part 1 requirements for development, validation and routine control of a sterilization process for medical devices Amendment - 1 | 20-09-2023 | No |
| 17. | MHD/12/23888 | Packaging for terminally sterilized medical devices Guidance on the application of ISO 11607-1 and ISO 11607-2 | 20-10-2023 | No |
| 18. | MHD/12/23591 | In vitro diagnostic medical devices Single-use containers for the collection of specimens from humans other than blood | 25-09-2023 | No |
| 19. | MHD/12/23261 | Prefilled syringes Part 4 Glass barrels for injectables and sterilized subassembled syringes ready for filling Amendment - 1 | 16-08-2023 | No |
| 20. | MHD/12/20820 | Sterile hypodermic syringes for single use Part 2: Syringes for use with power-driven syringe pumps | 25-07-2023 | No |
| 21. | MHD/12/23904 | Intravascular catheters Sterile and single-use catheters Part 6: Subcutaneous implanted ports | 20-10-2023 | No |
| 22. | MHD/12/23654 | Injection Containers and Accessories Part 7: Injection Caps Made of Aluminium-Plastics Combinations Without Overlapping Plastics Part | 25-09-2023 | No |
| 23. | MHD/12/18072 | STERILIZER INSTRUMENTS TABLE MODEL SPECIFICATION Fourth Revision | 26-06-2023 | No |
| 24. | MHD/12/23337 | Single-use Sterile Rubber Surgical Gloves-Specification | 17-09-2023 | No |

The documents where no comments have been received may be taken up for finalization.

*The Committee may kindly consider*

**ITEM 5DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDECIRCULATION**

5.1 There are currently no standard/amendment for approval for wide circulation .

*The Committee may kindly note.*

**ITEM 6DRAFT UNDER PREPARATION**

6.1There are currently no indigenous subject drafts under preparation.

*The Committee may kindly note.*

**ITEM 7COMMENTS ON PUBLISHED STANDARDS**

7.1 No comments have been received on published Indian Standards.

*The committee may kindly note.*

## ITEM 8NEW SUBJECTS

8.1 The committee may identify the emerging fields in the area under its scope and decideformulation of Indian Standards on the same. The Committee may also define thrust area which shouldtake into consideration the standards development required in the given context keeping in viewthe social, environmental and economic consideration.

*The Committee may kindly deliberate.*

## ITEM 9TECHNICAL ISSUES

9.2 The following technical issues on the Indian Standards need to be resolved:

| Sl. No. | Document No./ Standard No.& Title | Issues |
|---|---|---|
| 1. | MHD/12/14451: Specification for refrigerator or combined refrigerator and water pack freezer intermittent mains powered, compression cycle, general requiremnt and testing methods . | Technical Comments are attached in Annexure 2. |

## ITEM 10. INTERNATIONAL ACTIVITIES

**10.1** 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)

*The Committee may please note.*

**10.2** List of Adopted standards as per the ISO Committee in **Annexure 3.**

10.3 List of ISO Standards for adoption as an Indian Standards in Annexure 4.

**10.4**The details for the working groups of ISO/TC 76, ISO/TC 84 and ISO/TC 198 are given below:

*a) The working groups of ISO/TC 76 are given below:*

| *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 | 1) Sh. Manoj A, Terumopenpol Pvt. Ltd., Thiruvanthapuram<br>2) Dr. AseemSahu, CDSCO, New Delhi |
| 2 | ISO/TC 76/WG 2 | Rigid container systems and related accessories for parenterals and injectables | __ |
| 3 | ISO/TC 76/WG 4 | Elastomeric parts and components and related secondary packaging components | 1) Dr. AseemSahu, CDSCO, New Delhi |

*The committee may please note.*

*b) The working groups of ISO/TC 84 are given below:*

| *S. No.* | *Working Group* | *Title* | *Member* |
|---|---|---|---|
| 1 | ISO/TC 84/WG 3 | Needle-based injection systems - Injector, container and pen needle | 1)Sh. Narendra Kumar Jain IsconSurgicals, Jodhpur<br>2)Sh. Rajiv Nath, AIMED |
| 2 | ISO/TC 84/WG 8 | Sharps containers | 1)Sh. Rajiv Nath, AIMED<br>2) Sh. P K Sharma, AIMED |
| 3 | ISO/TC 84/WG 9 | Catheters | __ |
| 4 | ISO/ TC 84/ WG 10 | Needles | __ |
| 5 | ISO/TC 84/WG 11 | Syringes | 1)Sh. Narendra Kumar Jain IsconSurgicals, Jodhpur<br>2) Sh. Rajiv Nath, AIMED |
| 6 | ISO/TC 84/WG 16 | Drug delivery system requirements for pediatrics and other demographics | __ |

| | | | |
|---|---|---|---|
| 7 | ISO/TC 84/WG 17 | Specification and demonstration of reliability of single-use drug delivery systems | __ |

*The committee may please note.*

*c) The working groups of ISO/TC 198 are given below:*

| *S. No.* | *Working Group* | *Title* | *Member* |
|---|---|---|---|
| 1 | ISO/TC 198/WG 1 | Industrial ethylene oxide sterilization | 1)Sh. BansiDhurandhar, MicrotrolSterilisation Services Pvt. Ltd. (Mumbai)<br><br>2) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore |
| 2 | ISO/TC 198/WG 2 | Radiation sterilization | 1)Sh. BansiDhurandhar, MicrotrolSterilisation Services Pvt. Ltd. (Mumbai) |
| 3 | ISO/TC 198/WG 3 | Moist heat sterilization | __ |
| 4 | ISO/TC 198/WG 4 | Biological indicators | Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore |
| 5 | ISO/TC 198/WG 5 | Terminology | __ |
| 6 | ISO/TC 198/WG 6 | Chemical indicators | Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore |
| 7 | ISO/TC 198/WG 7 | Packaging | 1)Sh. Vishnu Vyas, Dupont, Gurgaon<br><br>2) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore |
| 8 | ISO/TC 198/WG 8 | Microbiological methods | __ |

| | | | |
|---|---|---|---|
| 9 | ISO/TC 198/WG 9 | Aseptic processing | — |
| 11 | ISO/TC 198/WG 12 | Information for reprocessing of re serializable devices | — |
| 12 | ISO/TC 198/WG 13 | Washer-disinfectors | — |

*The committee may please note.*

## ITEM 11. PROGRAMME OF WORK

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

*The Committee may kindly note.*

### 11.2 Review of Indian Standards (pre-2000 Standards)

11.2.1 All the Indian Standards published before the year 2000 need to be reviewed forrevision/withdrawal/archived in the light of technological developments that have happened so far inrelation to these standards.

11.2.2 The list of such Indian Standardsis given at***Annexure***- 5 are reviewd by 3M Medical system as per the in previous meeting decided.

11.2.3 The list of such Indian standards is given at *Annexure-6* are reviewed by Becton Dickinson Pvt. Ltd as per in previous meeting decided .

*The Committee may kindly review*.

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

11.3.1 As per the policy of BIS, the Indian Standards which have completed five years sincetheir last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for theirreaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far inrelation to these standards.

11.3.2 With a view to improve the quality of standards formulation process and making it more evidencebased, BIS envisions to undertake research and prepare a review document in respect of each ofthe Indian Standards which are due for revision.

11.3.3 The list of such Indian Standards which are due for review in 2023-24 is given at***Annexure*** 7.

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

## ITEM 12 ISSUES ARISING OUT OF THEPREVIOUS MEETINGS

12.1 No any issues arises out of the previous meeting

*The Committee may kindly note.*

## ITEM 13 Subject to be Transfer

13.1 The following standards are identified by BIS secretarieat for transfer from MHD12 to MHD 10 as it is more relevant to the scope of MHD 10

| S.no. | IS No. | Title | Scope | Recommendation |
|---|---|---|---|---|
| 1 | IS 15110 | Veterinary thermometers, mercury - In - Glass type - Specification | This standard covers maximum self-registering, mercury-in-glass reusable thermometers used for measuring animal body temperatures. | Transfer the standard from MHD 12 to MHD 10 |
| 2 | 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.<br>1.2 This specification applies to battery-powered instruments which provide a digital indication of temperature | Transfer the standard from MHD 12 to MHD 10 |

**The committee may kindly deliberate.**

## ITEM 14DATE AND PLACE OF NEXT MEETING

14.1 As per the approved Annual Meeting Calendar for 2023-24, the next meeting ofMHD 12 is scheduled on 05 Feb 2024 on Monday.

| **Quarter 1** | **Quarter 2** | **Quarter 3** | **Quarter 4** |
|---|---|---|---|
| 15 May 2023, Monday | 9 Aug 2023, Wednesday | 4 Sep 2023, Monday | 10 Nov 2023, Friday |

*The Committee may kindly note.*

**ITEM 15 ANY OTHER BUSINESS**

**Annexure 1**

*(Item No 2.2)*

Composition of Sectional Committee

| S.No. | Organization | Member Name | Last 3 Month Attendance |
|---|---|---|---|
| 1 | In Individual Capacity | Maj Gen Sunil Kant Vsm | 3/3 |
| 2 | 3M India Limited, Bengaluru | KULVEEN SINGH BALI | 2/3 |
| 3 | | Kavitha Kulkarni | |
| 4 | | Dr. PrabhaHegde | |
| 5 | All India Institute of Medical Sciences, New Delhi | Dr. ManjuNathMaruthi Pol | 0/3 |
| 6 | Asia Pacific Medical Technology Association (APACMed), Gurugram | Shri R. Ashok Kumar | 2/3 |
| 7 | | Sh. Parveen Jain | |
| 8 | | Shreya Bansal | |
| 9 | Association of Indian Medical Device Industry, New Delhi | Shri Kamlesh R. Shah | 0/0 |
| 10 | | Shri UpinderVishen | |
| 11 | | Ravi Abraham | |
| 12 | B. Braun Medical India Private Limited, New Delhi | Anmol Kumar Ray | 2/3 |
| 13 | | Arihant Jain | |
| 14 | Becton Dickinson India Private Limited, Gurugram | Shri Neeraj Sharma | 3/3 |
| 15 | | SudhakarMairpady | |
| 16 | Boston Scientific India Private Limited, Gurugram | PrashanthPrabhakar | 2/3 |
| 17 | | Dev Chopra | |
| 18 | Central Drugs Standard Control Organization, New Delhi | AseemSahu | 1/3 |
| 19 | | ShyamniSasidharan | |
| 20 | | Shri Pradeep | |
| 21 | E.I. DuPont India Private Limited, Gurugram | Shri. Vishnu Shankar Vyas | 2/3 |
| 22 | | Shri Srinivas S Cherukupalli | |
| 23 | ESIC Dental College and Hospital, Delhi | Dr. Jitin Kharbanda | 0/0 |
| 24 | | Dr Mansi atri | |
| 25 | Ganga Ram Hospital, New Delhi | Dr. Jyoti Randhawa | 0/3 |
| 26 | | Dr. Tarun Mittal | |
| 27 | Guru Teg Bahadur Hospital, New Delhi | DR. BHARAT B. SAGAR | 0/3 |

| | | | |
|---|---|---|---|
| 28 | HCL, Noida | Shri MakeshRamalingam | 2/3 |
| 29 | Haffkine Institute For Training, Research & Testing, Mumbai | Dr. Shashikant Vaidya | 1/3 |
| 30 | | DrSandeshaPashte | |
| 31 | Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad | Sh. Pradeep Sareen | 1/3 |
| 32 | Indian Institute of Technology Delhi, New Delhi | Pradeebasridar | 0/3 |
| 33 | | Aarat p Kalra | |
| 34 | | Naveen singh | |
| 35 | Indian Institute of Technology Kanpur, Kanpur | Dr J. Bera Chemistry | 0/3 |
| 36 | Indian Medical Association, New Delhi | Dr Anil Nayak | 1/3 |
| 37 | | Dr V. K. Monga | |
| 38 | | Dr. Jayesh M. Lele | |
| 39 | | DrSahajanand Prasad Singh | |
| 40 | Indian Pharmacopoeia Commission, Ghaziabad | Dr Anil kumarTeotia | 2/3 |
| 41 | | DrManoj Kumar Pandey | |
| 42 | | Dr. Anil Kumar Teotia | |
| 43 | Indian Rubber Gloves Manufacturers Association , New Delhi | Manmohan singhgulati | 0/0 |
| 44 | | Vikasanand | |
| 45 | | Naveen Kumar Reddy | |
| 46 | Iscon Surgicals Limited, Jodhpur | Shri Narendra Kumar Jain | 1/3 |
| 47 | | Shri Deepak Singhavi | |
| 48 | Johnson and Johnson Private Limited, Mumbai | Shri Shiv Kumar Hurdale | 1/3 |
| 49 | | Sh. Aaditya Vats | |
| 50 | | Ms. Aishwarya Nair | |
| 51 | Kalam Institute of Health Technology, Vishakhapatnam | Dilip Kumar Chekuri | 2/3 |
| 52 | | Sushmita Roy Chowdhury | |
| 53 | | Syed Mustafiz Ahmed | |
| 54 | Lady Irwin College, New Delhi | DrBhawanaChanana | 1/3 |
| 55 | | DrSheetal Chopra | |
| 56 | Maulana Azad Medical College, New Delhi | Dr. Deepak Ghuliani | 0/3 |
| 57 | | Anurag Mishra | |
| 58 | Microtrol Sterilisation Services Private Limited, Mumbai | Bansidhar S. Dhurandhar | 2/3 |
| 59 | | Manoj Mishra | |
| 60 | | Shri RANJEET V. KALIA | |
| 61 | Paramount Surgimed Limited, New Delhi | Shri Shaily Grover | 1/3 |
| 62 | | Shri Abhay Kumar | |
| 63 | | Shri Abhay Kumar | |
| 64 | Post Graduate Institute of Medical Education and Research, Chandigarh | Shri Sanjeev Sharma | 2/3 |
| 65 | | Dr. Shweta Talati | |
| 66 | | Dr.Navneet Dhaliwal | |
| 67 | Shriram Institute for Industrial Research, Delhi | Ajeet Kr. Agrawal | 1/3 |
| 68 | | Dr. Binu Bhat | |
| 69 | Stryker India Private Limited, Gurugram | Mr. Shivkumarhurdale | 1/3 |
| 70 | Terumo Penpol Private Limited, Thiruvananthapuram | Manoj A. | 3/3 |
| 71 | | V M Shajahan | |

**Annexure 2**
*(Item 2.2)*

Comments Received on MHD/12/14451- Specification for Refrigerator or Combined Refrigerator and Water-Pack Freezer Intermittent Mains Powered: Compression Cycle General requirement and testing methods .

| Clause | Sub clause | Modifications | Refrences |
|---|---|---|---|
| 4 REQUIREMENTS 4.1 General (Physical Characteristics) | 4.1.2 | Overall Dimensions<br>To allow for manoeuvring 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 | PQS performance specification WHO/PQS/E 003/RF03.5 |
| 3. **Terms and Definitions** | - | **(a) User-dependent freeze protection (UDFP):** Refrigeration technology that requires appliance users (e.g., health care workers) to perform specific actions (user interventions) in order to ensure vaccine protection against freezing temperatures (e.g., store vaccines in baskets, away from compartment wall surfaces).<br>**(b) User-independent freeze protection (UIFP)**: Refrigeration technology that requires appliance users (e.g., health care workers) to perform no specific actions (user interventions) in order to ensure vaccine protection against freezing temperatures.<br>**(c) User Interventions**: Any activity that | PQS performance specification WHO/PQS/E 003/RF03.5 |

| | | | |
|---|---|---|---|
| | | is required to be executed by appliance user in order to ensure vaccine protection against freezing. Activities could include, but are not limited to, basket storage, storage compartment covers and thermostat adjustment | |

**DESIGNCONSIDERATIONS:**

- **Corrosionresistance:**ReliabilityshouldnotbesolelyonMetal/GalvanizedsteelI LRbodies,wemustalso lookat other optionslike:RotomoldedPolypropylene:

  Rotomolded PE has Excellent resistance to corrosion and decay, Not only no chance ofrusting, but also copes with an amazing range of corrosive chemicals that can eat throughgalvanizedsteel.
  Moreover, Galvanized steel can catch rust if any scratch or abrasion occurs, as hot dipgalvanizedsteelismoreresistanttorusting thanaconventionalgalvanized steel. In rotomolding we don't have any joints or riveting to hold the body together. whereas incase of a galvanized body, rusting may occur at welded points and the riveted points, ThebodyofTCW3000 isasinglerotomoldedpart, hencenojoints orwelds.

  With galvanized steel bodies, care needs to be taken not to rip the inner poly lining, thuscompromising the performance of the ILR and stored vaccines may lose their efficacy ifexposed to temperatures beyond their storage temperatures. but that is not the case withrotomoldedbodies.

  **For Corrosion Testing:** The ILR bodies must sustain at least 96 hours of salt spray testas specified in ISO 9000 (Part-XI) and for components, following standards can also beused/referred **EN ISO 6270-1 / ASTM D2247 / EN 13523-26, EN ISO 6270-2 / EN13523-25,ISO6272 / EN13523-5**and**ISO2409.**

- **Insulation:**it'spreferredtohavefoamdensity≥32g/dm3forbetterholdover

- **Gaskets:**Doublegasketdesigntoensure noheat infiltrationoccurs.

- **Innerlining:**for ILR'sitspreferred touseAluminuminner-linersasitsthermalconductivityissuperiorto steel

- **OperatingAmbientTemperatureRange:**mustbedesigned tobeoperated atambienttemperature of +5℃ to +43℃, looking at the varied ambient temperature range acrossIndia movingfromUpNorth toDown SouthandfromWeastto EastIndia.

- **TransportationandstorageTemperatureRange**,TheILRsmustsustaintemperatu resof-30℃to +55℃and RHof5%to95%(non-condensing)

- **Temperature data-logging and Monitoring:** There should be provision to retrievehistorical data of at least 30 days and it's good to have Continuous temperature monitorcapabilitiesanddatashould beprotected asper21 CFR.

- **HFC/HCFCfreerefrigerants:**ILR'sarerequired touseHCrefrigerants suchasR600aorothergases withGWP≤11andzeroozonedepletionpotential(ODP).

- **TemperatureDisplay:**Digital displaypanel shouldbe providedwithresolutionof0.1℃

- **Thermostat:**Electrical/Electronicthermostatsshouldbeused.Mechanicalthermostatsshou ldnotbeused forbetteraccuracy.

**PERFORMANCE&TESTINGCONSIDERATIONS:**

- **IntermittentPower:**LookingatPowerinfrastructureinIndia, speciallyforrulerarea,The machine should perform as specified provided with 12 Hours/16 Hours ofcontinuouspowerand 12Hours/8Hoursin24 hourday cycle. (IntermittentPower* :12hoursON-12hoursOffor16HoursON-8HoursOff)

- **Holdover:**ILRsshouldbeabletoprovideholdover (Tomaintaintemperaturesindesiredrange, 2℃ to 8℃) for ≥ 24 hours. No temperature excursion should happen below 2℃andabove8℃

- **Day/NightTest:**tobeconductedbyVarying theambienttemperaturefrom 43to25Commencing with the start of the intermittent power* (Refer above) phase begin.witha12-hourday phase ofa24-hour solarcycle holdthe temperatureo thetestchamberto+43°C,for a further 12hours.Thenlower thetemperature to25ºCovera3 hourperiod. Holdat +25ºC forafurther9 hours. Next raisetheambienttemperature to:+43°Covera further 3hourperiod. +43ºCfor a further9hours.Repeatthissimulatedday-nightcycleforfivecomplete24-hourcyclesintotal.

- **Energy Consumption Test:** to be performed at the highest operating ambienttemperature(+43 ℃) andpowerconsumptionvaluestobedeclared accordingly.

- **ElectricalSafety:**manufacturermust/shouldcertifycompliancewith**IEC60335-1,IEC60335-2-24**

- **EMI/EMC:**manufacturermust/shouldcertify compliancewith**61000-6-1, IEC61000-6-3**

- **Cool down &Initial stabilization test:** Cooldown to be performed at intermittentpower*(Referabove).NoStandard tobesetforminimumtimerequiredforcooldown,manufacturer has to declare thetimerequiredforcool down.

  Initialstabilizationisaccomplishedwhen theappliancedemonstratesallthefollowing:

The thermal storage has been cooled for a period no less than the cool down time periodstated in the instructions provided by the manufacturer. (e.g., if instructions state cooldown time is 3 days, then at least a 3-day cool down test is required); The internaltemperatures in the vaccine storage compartment are within the acceptable temperaturerange;and Thecoolingsystem hasexhibitedconsistenton/offoperationforthe,finaltwodays of thistest(e.g.thesame numberofon/offcyclesper dayforthefinaltwodays).

**FreezeProtectionclassification:**ILR'sshouldbeclassifiedintocategoriesasspecifiedby WHO:

**Grade A,** user-independent freeze protection (UIFP): When the appliance is used withinits nominated temperature range (temperature zone +43°C,+32°C or +27°C and minimumrated ambient temperature) there is no intervention required by the user to ensure that thevaccines will not be exposed to temperatures below 0°C whatever the position of thevaccine inthevaccinecompartment.

**Grade B,** user-dependent freeze protection (UDFP): Even if the appliance is used withinits nominated temperature range, the user must comply with a procedure provided by themanufacturer and requiring one level of intervention (e.g., the requirement to use basketsorotheritems)to avoidvaccinefreezing.

**Grade C,** user-dependent freeze protection (UDFP): Even if the appliance is used withinits nominated temperature range, the user must comply with a procedure provided by themanufacturer requiring more than one level of intervention in order to avoid vaccinefreezing.(e.g.,therequirementtouse basketsandinsulationbarriersorcovers)

Minimumratedambienttemperature

Allmodelsmustbe testedtooperate ataconti nuousminimumambienttemperature of +5.0°Cwhilstmaintainingtheacceptabletemperaturerange of +2°Cto+8°C.

## Annexure 3

(Item 10.2)
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.

| Sr.no | ISO No. | Title | Status |
|---|---|---|---|
| 1. | ISO 719:2020 | Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification | Adopted |
| 2. | ISO 720:2020 | Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification | Adopted |
| 3. | ISO 1135-3:2016 | Transfusion equipment for medical use — Part 3: Blood-taking sets for single use | Adopted |
| 4. | ISO 1135-4:2015 | Transfusion equipment for medical use — Part 4: Transfusion sets for single use, gravity feed | Adopted |
| 5. | ISO 1135-5:2015 | Transfusion equipment for medical use — Part 5: Transfusion sets for single use with pressure infusion apparatus | Not adopted |
| 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 |
| 8. | ISO 3826-1:2019/Amd 1:2023 | Plastics collapsible containers for human blood and blood components — Part 1: Conventional containers — Amendment 1 | Under Development |

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| 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 |
| 10. | ISO 3826-3:2006 | Plastics collapsible containers for human blood and blood components — Part 3: Blood bag systems with integrated features | Adopted |
| 11. | ISO 3826-4:2015 | Plastics collapsible containers for human blood and blood components — Part 4: Aphaeresis blood bag systems with integrated features | Adopted |
| 12. | ISO 4802-1:2016 | Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification | Adopted |
| 13. | ISO 4802-2:2016 | Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification | Adopted |
| 14. | ISO 6710:2017 | Single-use containers for human venous blood specimen collection | Adopted |
| 15. | ISO 6717:2021 | In vitro diagnostic medical devices — Singleuse containers for the collection of specimens from humans other than blood | Under development |
| 16. | ISO 8362-1:2018 | Injection containers and accessories — Part 1: Injection vials made of glass tubing | Doc in print |
| 17. | ISO 8362-2:2015 | Injection containers and accessories — Part 2: Closures for injection vials | Doc in print |
| 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 |
| 20. | ISO 8362-4:2011 | Injection containers and accessories — Part 4: Injection vials made of moulded glass | Adopted |
| 21. | ISO 8362-5:2016 | Injection containers and accessories — Part 5: Freeze drying closures for injection vials | Under Development |
| 22. | ISO 8362-6:2010 | Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials | Under Development |
| 23. | ISO 8362-7:2006 | Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part | Under Development |
| 24. | ISO 8536-1:2011 | Infusion equipment for medical use — Part 1: Infusion glass bottles | Adopted |

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| 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 |
| 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 transfusion and infusion equipment without fluid contact | Not adopted |
| 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 |

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| 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 | Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: | Not adopted |
| | 1:2018 | Determination of released-particle count— Amendment 1 | |
| 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 |
| 49. | ISO 9187-2:2010 | Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules | Doc in print |
| 50. | ISO 11040-1:2015 | Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges | Adopted |
| 51. | ISO 11040-2:2011 | Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges | Adopted |
| 52. | ISO 11040-3:2012 | Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges | Adopted |
| 53. | ISO 11040-4:2015 | Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling | Adopted |
| 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 | Under Development |
| 55. | ISO 11040-5:2012 | Prefilled syringes — Part 5: Plunger stoppers for injectables | Adopted |
| 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 |

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| 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 |
| 60. | ISO 11418-2:2016 | Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups | Adopted |
| 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 |
| 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 |
| 66. | ISO 114187:2016 | Containers and accessories for pharmaceutical preparations — Part 7: Screw-neck vials made of glass tubing for liquid dosage forms | Adopted |
| 67. | ISO 139261:2018 | Pen systems — Part 1: Glass cylinders for pen-injectors for medical use | Adopted |
| 68. | ISO 139262:2017 | Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use | Adopted |
| 69. | ISO 13926-3:2019 | Pen systems — Part 3: Seals for pen-injectors for medical use | Docs in print |
| 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 |

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| 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 |
| 74. | ISO 15747:2018 | Plastic containers for intravenous injections | Under Development |
| 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 24166-1:2022 | Snap-on bottles for metering pumps — Part 1: Tubular glass | Not adopted |
| 82. | ISO 241662:2022 | Snap-on bottles for metering pumps — Part 2: Moulded glass | Not adopted |
| 83. | ISO 241663:2022 | Snap-on bottles for metering pumps — Part 3: Plastic | Not adopted |
| 84. | 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 |
|---|---|---|---|
| 1. | ISO/TS 5111:2022 | Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products | Under Development |
| 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 |
| 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 |
| 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 | Under Development |
| 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 | Not adopted |
| 7. | ISO 11137-2:2013 | Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose | Adopted |

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| 8. | ISO 11137-2:2013/Amd 1:2022 | Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose — Amendment 1 | Under Development |
| 9. | ISO 11137-3:2017 | Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control | Adopted |
| 10. | ISO/TS 111374:2020 | 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 |
| 12. | ISO 11138-2:2017 | Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes | Adopted |
| 13. | ISO 11138-3:2017 | Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes | Adopted |
| 14. | ISO 11138-4:2017 | Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes | Adopted |
| **15.** | ISO 11138-5:2017 | Sterilization of health care products — Biological indicators — Part 5: Biological indicators for lowtemperature steam and formaldehyde sterilization processes | Adopted |
| **16.** | ISO 11138-7:2019 | Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results | Under Development |
| **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 | Under Development |
| **18.** | ISO 11139:2018 | Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards | Adopted |
| **19.** | ISO 11140-1:2014 | Sterilization of health care products — Chemical indicators — Part 1: General | Under development |

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| | | requirements | |
| **20.** | ISO 11140-3:2007 | Sterilization of health care products — | Adopted |
| | | Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test | |
| **21.** | 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 |
| **22.** | 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 |
| **23.** | 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 |
| **24.** | 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 | Under Development |
| **25.** | ISO 11607-1:2019 | Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems | Adopted |
| **26.** | ISO 11607-2:2019 | Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes | Adopted |
| **27.** | ISO 11737-1:2018 | Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products | Adopted |
| **28.** | 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 | Under Development |

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| **29.** | 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 |
| **30.** | ISO 11737-3:2023 | Sterilization of health care products — Microbiological methods — Part 3: Bacterial endotoxin testing | Not adopted |
| **31.** | ISO 13004:2022 | Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD | Not adopted |
| **32.** | ISO 13408-1:2008 | Aseptic processing of health care products — Part 1: General requirements | Adopted |
| **33.** | ISO 13408-1:2008/Amd 1:2013 | Aseptic processing of health care products — Part 1: General requirements — Amendment 1 | Adopted |
| **34.** | ISO 13408-2:2018 | Aseptic processing of health care products — Part 2: Sterilizing filtration | Adopted |
| **35.** | ISO 13408-3:2006 | Aseptic processing of health care products — Part 3: Lyophilization | Not adopted |
| **36.** | ISO 13408-4:2005 | Aseptic processing of health care products — Part 4: Clean-in-place technologies | Not adopted |
| **37.** | ISO 13408-5:2006 | Aseptic processing of health care products — Part 5: Sterilization in place | Not adopted |
| **38.** | ISO 13408-6:2021 | Aseptic processing of health care products — Part 6: Isolator systems | Not adopted |
| **39.** | ISO 13408-7:2012 | Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products | Not adopted |
| **40.** | ISO 14160:2020 | Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices | Under Development |

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| **41.** | 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 |
| **42.** | ISO 15882:2008 | Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results | Under development |
| **43.** | ISO 15883-1:2006 | Washer-disinfectors — Part 1: General requirements, terms and definitions and tests | Adopted |
| **44.** | ISO 15883-1:2006/Amd 1:2014 | Washer-disinfectors — Part 1: General requirements, terms and definitions and tests — Amendment 1 | Not adopted |
| **45.** | 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 |
| **46.** | ISO 15883-3:2006 | Washer-disinfectors — Part 3: Requirements and tests for washerdisinfectors employing thermal disinfection for human waste containers | Adopted |
| **47.** | ISO 15883-4:2018 | Washer-disinfectors — Part 4: Requirements and tests for washerdisinfectors employing chemical disinfection for thermolabile endoscopes | Docs in print |
| **48.** | ISO 15883-5:2021 | Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy | Docs in print |
| **49.** | 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 |

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| **50.** | 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 |
| **51.** | ISO/TS 16775:2021 | Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2 | Adopted |
| **52.** | 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 |
| **53.** | 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 |
| **54.** | 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 | Docs in print |
| **55.** | ISO/TS 176652:2009 | Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1 | Not adopted |
| **56.** | ISO/TS 176653:2013 | 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 |
| **57.** | ISO 18362:2016 | Manufacture of cell-based health care products — Control of microbial risks during processing | Not adopted |
| **58.** | ISO 18362:2016/Amd 1:2022 | Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1 | Not adopted |

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| **59.** | ISO 18472:2018 | Sterilization of health care products — Biological and chemical indicators — Test equipment | Not adopted |
| **60.** | ISO/TS 19930:2017 | Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6 | Adopted |
| **61.** | ISO 20857:2010 | Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices | Not adopted |
| **62.** | ISO/TS 21387:2020 | Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release | Adopted |
| **63.** | 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 |
| **64.** | 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 |
| **65.** | ISO/TS 22456:2021 | Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products | Not adopted |
| **66.** | ISO 25424:2018 | Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices | Not adopted |

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| **67.** | ISO 25424:2018/Amd 1:2022 | Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1 | Not adopted |

# 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 |
|---|---|---|---|
| 1. | ISO 6009:2016 | Hypodermic needles for single use — Colour coding for identification | Adopted |
| 2. | ISO 7864:2016 | Sterile hypodermic needles for single use — Requirements and test methods | Adopted |
| 3. | ISO 7886-1:2017 | Sterile hypodermic syringes for single use — Part 1: Syringes for manual use | Adopted |
| 4. | ISO 7886-2:2020 | Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps | Not adopted |
| 5. | ISO 7886-3:2020 | Sterile hypodermic syringes for single use — Part 3: Auto-disabled syringes for fixed-dose immunization | Adopted |
| 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 |
| 8. | ISO 9626:2016 | Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods | Not adopted |
| 9. | ISO 10555-1:2013 | Intravascular catheters — Sterile and singleuse catheters — Part 1: General requirements | Adopted |
| 10. | ISO 10555-1:2013/Amd 1:2017 | Intravascular catheters — Sterile and singleuse catheters — Part 1: General requirements — Amendment 1 | Under development |
| 11. | ISO 10555-3:2013 | Intravascular catheters — Sterile and singleuse catheters — Part 3: Central venous catheters | Adopted |

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| 12. | ISO 10555-4:2013 | Intravascular catheters — Sterile and singleuse catheters — Part 4: Balloon dilatation catheters | Adopted |
| 13. | ISO 10555-5:2013 | Intravascular catheters — Sterile and singleuse catheters — Part 5: Over-needle peripheral catheters | Adopted |
| 14. | ISO 10555-6:2015 | Intravascular catheters — Sterile and singleuse catheters — Part 6: Subcutaneous implanted ports | Under development |
| 15. | ISO 10555-6:2015/Amd 1:2019 | Intravascular catheters — Sterile and singleuse catheters — Part 6: Subcutaneous implanted ports — Amendment 1 | Not adopted |
| 16. | ISO 11070:2014 | Sterile single-use intravascular introducers, dilators and guidewires | Under development |
| 17. | ISO 11070:2014/Amd 1:2018 | Sterile single-use intravascular introducers, dilators and guidewires — Amendment 1 | Not adopted |
| 18. | ISO 116081:2022 | Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems | Not adopted |
| 19. | ISO 116082:2022 | Needle-based injection systems for medical use — Requirements and test methods — Part 2: Double-ended pen needles | Not adopted |
| 20. | ISO 116083:2022 | Needle-based injection systems for medical use — Requirements and test methods — Part 3: Containers and integrated fluid paths | Not adopted |
| 21. | ISO 116084:2022 | Needle-based injection systems for medical use — Requirements and test methods — Part 4: Needle-based injection systems containing electronics | Not adopted |
| 22. | ISO 116085:2022 | Needle-based injection systems for medical use — Requirements and test methods — Part 5: Automated functions | Not adopted |
| 23. | ISO 116086:2022 | Needle-based injection systems for medical use — Requirements and test methods — Part 6: On-body delivery systems | Not adopted |
| 24. | ISO 116087:2016 | 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 |

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|---|---|---|---|
| 26. | ISO/TR 19244:2014 | Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters | Not adopted |
| 27. | ISO 20069:2019 | Guidance for assessment and evaluation of changes to drug delivery systems | Under development |
| 28. | ISO 20072:2009 | Aerosol drug delivery device design | Not adopted |
| | | verification — Requirements and test methods | |
| 29. | ISO 20695:2020 | Enteral feeding systems — Design and testing | Not adopted |
| 30. | ISO 20696:2018 | Sterile urethral catheters for single use | Adopted |
| 31. | ISO 20697:2018 | Sterile drainage catheters and accessory devices for single use | Under print |
| 32. | ISO 20698:2018 | Catheter systems for neuraxial application — Sterile and single-use catheters and accessories | Under development |
| 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 | Under print |
| 35. | ISO 23907-2:2019 | Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers | Under developmet |
| 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 | Under development |

Annexure 4
*(Item 10.3)*

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

| S.No. | ISO No. | Title |
|---|---|---|
| 1. | ISO 8536-2:2023 | Infusion equipment for medical use — Part 2: Closures for infusion bottles |
| 2. | ISO 8536-3:2009 | Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles |
| 3. | ISO 8536-3:2009/Amd 1:2022 | Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles — Amendment 1 |
| 4. | ISO 8536-5:2004 | Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed |
| 5. | ISO 8536-6:2016 | Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles |
| 6. | ISO 8536-7:2009 | Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles |
| 7. | ISO 8536-8:2015 | Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus |
| 8. | ISO 8536-9:2015 | Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment |
| 9. | ISO 8536-10:2015 | Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment |
| 10 | ISO 8536-11:2015 | Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment |
| 11 | ISO 8536-12:2021 | Infusion equipment for medical use — Part 12: Check valves for single use |
| 12 | ISO 8536-13:2016 | Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact |
| 13 | ISO 8536-14:2016 | Infusion equipment for medical use — Part 14: Clamps and flow regulators for transfusion and infusion equipment without fluid contact |
| 14 | ISO 8536-15:2022 | Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use |
| 15 | ISO 8536-15:2022/Amd 1:2023 | Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use — Amendment 1 |

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|---|---|---|
| 16 | 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 |
| 17 | ISO 13408-3:2006 | Aseptic processing of health care products — Part 3: Lyophilization |
| 18 | ISO 13408-4:2005 | Aseptic processing of health care products — Part 4: Clean-in-place technologies |
| 19 | ISO 13408-5:2006 | Aseptic processing of health care products — Part 5: Sterilization in place |
| 20 | ISO 13408-6:2021 | Aseptic processing of health care products — Part 6: Isolator systems |
| 21 | ISO 13408-7:2012 | Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products |
| 22 | ISO 6009:2016 | Hypodermic needles for single use — Colour coding for identification |
| 23 | ISO 7886-2:2020 | Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps |
| 24 | ISO 11070:2014/Amd 1:2018 | Sterile single-use intravascular introducers, dilators and guidewires — Amendment 1 |
| 25 | ISO 239071:2019 | Sharps injury protection — Requirements and test methods — Part 1: Single-use sharps containers |
| 26 | ISO 239072:2019 | Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers |
| 27 | 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 |

Annexure 5
*(ITEM 11.2.2)*

| Sr No | IS Number | Title | Remarks from 3M Medical System . |
|---|---|---|---|
| 1 | IS B8462 : 1977 | Sterilizer, Portable, Vertical, Pressure Type (BILINGUAL) | We can reaffirm this standard. |
| 2 | IS 10150 : 1981 | Guide for sterilization of medical products | This Standard is outdated.committee may withdraw the standard. |
| 3 | IS 12430 : 1987 | Safety code for installation, servicing maintenance and of sterilizers | We can reaffirm this standard. |
| 4 | IS 3119 : 1978 | Specification for hot air sterilizers (First Revision) | We can reaffirm this standard. |
| 5 | 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) | We can reaffirm this standard. |
| 6 | IS 3829 (Part 2) : 1978 | Specification for steam sterilizers: Part 2 horizontal cylindrical high speed steam sterilizers, pressure type (First Revision) | We can reaffirm this standard. |
| 7 | IS 3829 (Part 3) : 1985 | Specification for steam sterilizers: Part 3 pressure sterilizers, vertical cylindrical type | We can reaffirm this standard. |
| 8 | IS 3831 : 1979 | Specification for sterilizer, shallow (Dressing Drum) | We can reaffirm this standard. |
| 9 | IS 5022 : 1989 | Sterilizer, instruments, table model (Third Revision) | We can reaffirm this standard. |
| 10 | IS 5035 : 1969 | Specification for sterilizers, bowl and utensil (Pedal Type) | We can reaffirm this standard. |
| 11 | IS 7455 : 1974 | Specification for sterilizer, pressure, hot and cold water | We can reaffirm this standard. |
| 12 | IS 8462 : 1977 | Specification for sterilizer, portable, vertical, pressure type | We can reaffirm this standard. |

Annexure 6
*(ITEM 11.2.3)*

| Sr No | IS Number | Title | Remark |
|---|---|---|---|
| 1 | IS 10985 : 1984 | Specification for needle, acupuncture | We can reaffirm this standard. |
| 2 | IS 11043 : 1984 | Specification for needle, epidural | We can reaffirm this standard. |
| 3 | IS 11400 : 1985 | Specification for hypodermic syringes, interchangeable type for general purposes | We can reaffirm this standard. |
| 4 | IS 12050 : 1986 | Specification for sterile hypodermic syringes with needle attached for single use | We can reaffirm this standard. |
| 5 | IS 3236 : 1992 | Hypodermic syringes for general purposes - Specification (Second Revision) | We can reaffirm this standard. |
| 6 | IS 3237 (Part 1) : 1985 | Specification for special purpose syringes: Part 1 insulin syringes (Second Revision) | We can reaffirm this standard. |
| 7 | IS 3237 (Part 2) : 1985 | Specification for special purpose syringes: Part 2 tuberculin syringes (Second Revision) | We can reaffirm this standard. |
| 8 | IS 3237 (Part 3) : 1985 | Specification for special purpose syringes: Part 3 bcg syringes (Second Revision) | We can reaffirm this standard. |
| 9 | IS 3237 (Part 4) : 1986 | Specification for special purpose syringes: Part 4 vaccine syringe | We can reaffirm this standard. |
| 10 | IS 3237 (Part 5) : 1986 | Specification for special purpose syringes: Part 5 post operation care syringe (Second Revision) | We can reaffirm this standard. |
| 11 | IS 3237 (Part 6) : 1986 | Specification for special purpose syringes: Part 6 irrigation syringe | We can reaffirm this standard. |
| 12 | IS 3237 (Part 7) : 1986 | Specification for special purpose syringe: Part 7 forced feeding syringe | We can reaffirm this standard. |
| 13 | IS 3237 (Part 8) : 1986 | Specification for special purpose syringes: Part 8 angiography syringe | We can reaffirm this standard. |
| 14 | IS 7350 : 1974 | Specification for needles, spinal | We can reaffirm this standard. |
| 15 | IS 7387 : 1974 | Needle, Biopsy, Liver, Silverman's Pattern | We can reaffirm this standard. |

# Annexure7

*(Item No 10.3.3)*

| S.No. | IS Number | IS Title | Due Date |
|---|---|---|---|
| 1 | IS 10654: 2018 ISO 7864 : 2016 | Sterile hypodermic needles for single use - Requirements and test methods (Fourth Revision) | December, 2023 |
| 2 | IS 12173 : 1987 | Specification for cervical halter | September, 2023 |
| 3 | IS 12430 : 1987 | Safety code for installation, servicing maintenance and of sterilizers | July, 2023 |
| 4 | IS 13422 : 1992 | Disposable surgical rubber gloves specification | June, 2023 |
| 5 | IS 7081 : 1973 | Specification for stool, revolving, for hospital use | March, 2024 |
| 6 | IS 7350 : 1974 | Specification for needles, spinal | September, 2023 |
| 7 | IS 7387 : 1974 | Needle, Biopsy, Liver, Silverman's Pattern | August, 2023 |
| 8 | IS 9824 (Part 1) : 1996 ISO 1135-1 | Transfusion equipment for medical use - Specification: Part 1 glass transfusion bottles, closures and caps (First Revision) | October, 2023 |
| 9 | IS/ISO 11607 : 2019 | Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems First Revision | March, 2024 |
| 10 | IS/ISO 11607 : 2019 | Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision) | March, 2024 |
| 11 | IS/ISO 8536-4 : 2019 | Infusion equipment for medical use Part 4: Infusion sets for single use gravity feed | March, 2024 |
| 12 | IS/ISO 3826-1 : 2019 | Plastics collapsible containers for human blood and blood components Part 1 Conventional containers First Revision | March, 2024 |
| 13 | IS/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 | March, 2024 |