MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
BUREAU OF INDIAN STANDARDS
AGENDA

Meeting	***Day & Date***	***Time***
11th Meeting of Hospital Surgical Equipment and Disposable Products Sectional Committee	Friday, 9th Aug 2023	02:00 pm
Meeting Link : https://bismanak.webex.com/bismanak/j.php?MTID=m8dd4566d7bcf78789b6554d63fd74961 **Meeting ID :2516 144 8794** **Password : Mhd@12**		

Chairperson: Lt Gen Sunil Kant (In-Personal capacity)
Member Secretary: Ms. Harshada Kadam

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

0.2 OPENING REMARKS BY THE CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE LAST MEETING

The minutes of the 10th meeting of Hospital Equipment and Surgical Disposable Products

Sectional Committee MHD 12 held on 15/05/2023 via WebEx Platform were circulated vide MHD 12/A2.10 dated 14.06.2023.

No comments have been received.

The committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF HOSPITAL EQUIPMENT AND SURGICAL DISPOSAL SECTIONAL COMMITTEE MHD 12

2.1 The scope of Hospital Equipment and Surgical Disposal Sectional Committee, MHD 12 is given below:

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

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 2/3rd 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- Non-active members to be withdrawn and young professionals who can contribute in the working of the committee may be co-opted.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.

2.4 Co-option received

Sr.No	**Organization/ Manufacturer**
1	Ansell Pvt.Ltd
2	Q & M Halyard Pvt. Ltd

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 (16276) Revision of: IS/ISO 8362:2003	Injection containers and accessories Part 1 Injection vials made of glass tubing Fourth Revision
2.	MHD 12 (16277) Revision of: IS 1984:2003	Injection containers and accessories Part 2 Injection vials made of moulded glass Third Revision

3.	MHD 12 (16286)	Pen systems Part 3 Seals for pen-injectors for medical use
4.	MHD 12 (17032)	Washer-disinfectors Part 4 Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes
5.	MHD 12 (17148)	Single-use medical examination gloves Part 1 Specification for gloves made from rubber latex or rubber solution Second Revision
6.	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
7.	MHD 12 (19189)	Sterile urethral catheters for single use
8.	MHD 12 (20819)	Injection equipment for medical use Part 2 One-point-cut OPC ampoules
9.	MHD 12 (20822)	Intravascular catheters Sterile and single-use catheters Part 6 Subcutaneous implanted ports

The committee may please note.

ITEM 5 DRAFT INDIAN STANDARDS FOR FINALIZATION

SI. No.	Doc No	TITLE
1	MHD 12 (19191)	Catheter systems for neuraxial application Sterile and single-use catheters and accessories
2	MHD 12 (20825)	Sterilization of health care products Biological indicators Part 7 Guidance for the selection use and interpretation of results
3	MHD 12 (20826)	Sterilization of health care products Biological indicators Part 8 Method for validation of a reduced incubation time for a biological indicator
4	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
5	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
6	MHD 12 (20837)	Washer-disinfection Part 5 Performance requirements and test method criteria for demonstrating cleaning efficacy

The committee may please finalize the documents for publication.

ITEM 6 DOCUMENT FOR APPROVAL FOR WIDE CIRCULATION

Sr. No	ISO Title	Remarks
1	Specification for Sterilizers shallow dressing drum	P draft completed on 21-04-

	Third Revision (18071)	2023
2	STERILIZER PORTABLE VERTICAL PRESSURE TYPE SPECIFICATION First Revision (18073)	P draft completed on 21-04-2023

The committee may please note.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

Organization	Comments Received
Ansell Pvt.Ltd	The Indian Standard for Surgical Gloves IS 13422:1992 has reference of ASTM D3577:1988. However, ASTM D3577 has been revised by ASTM D3577:2019.
MTaI ,Mun India and Kanam Latex Pvt Ltd	Comments received on IS 15354, Details are provided in **ANNEX 2.**
Q & M Halyard Pvt Ltd	Comment received on IS 15354-1:2018

The committee may note.

ITEM 8 NEW SUBJECTS

Organization	New Proposal topic
Q & M Halyard	ASTM D6978-05(2019) :Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs

The committee may note.

ITEM 9 TECHNICAL ISSUES

Sr. No	Doc No	Title
1.	MHD/12/14451	Ice -lined Refrigerator (ILR) for temperature range of -15c to -25c
2.	MHD/12/13693	Vaccine Carriers
3.	MHD/12/14449	Walk in cooler

The committee may deliberate.

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 equipment for medical and pharmaceutical use'	: (P-member)
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 **ANNEX 3.**

10.3 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 2) Dr. Ravi Kant Sharma, 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. Ravi Kant Sharma, 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 Iscon Surgicals, Jodhpur 2)Sh. Rajiv Nath, AIMED

2	ISO/TC 84/WG 8	Sharps containers	1)Sh. Rajiv Nath, AIMED 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 Iscon Surgicals, Jodhpur 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. Bansi Dhurandhar, Microtrol Sterilisation Services Pvt. Ltd. (Mumbai) 2) Sh. Kulveen Singh Bali,3 M India Ltd., Bangalore
2	ISO/TC 198/WG 2	Radiation sterilization	1)Sh. Bansi Dhurandhar, Microtrol Sterilisation 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 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 Products Sectional Committee, MHD 12 is available at BIS website www.bis.gov.in

The committee may please note.

11.2 The BIS management has taken a policy decision to withdraw all those Indian Standards which are no more required by the industry / trade in view of present day scenario. The committee may examine the Standards given in the POW in the light of latest technological development and technology/ industrial trend world over as well as their application to the Indian industries and consider for their revision / amendment / withdrawal, if required.

The committee may please note.

11.3 REVIEW/REAFFIRMATION OF PUBLISHED INDIAN STANDARDS

As per the policy of BIS, the Indian Standards, which have completing five years since their last Publication/reaffirmation, are to be reviewed by the concerned sectional committee for their reaffirmation for a further period of five years, if the standard is still required.

The list of standards due for Reaffirmation for a further period of 5 years is given below:

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 15354 (Part 1) : 2018ISO 11193-1 : 2008	Single - Use medical examination gloves: Part 1 specification for gloves made from rubber latex or rubber solution (First Revision)	December, 2023
11	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
11	IS/ISO 11607 : 2019	Packing for Terminally Sterilized Medical Devices Part 2 Validation Requirements for Forming Sealing and Assembly Processes (First Revision)	March, 2024
12	IS/ISO 8536-4 : 2019	Infusion equipment for medical use Part 4: Infusion sets for single use gravity feed	March, 2024
13	IS/ISO 3826-1 : 2019	Plastics collapsible containers for human blood and blood components Part 1 Conventional containers First Revision	March, 2024
14	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

The committee may please deliberate.

11.4 The list of Indian Standards (along with their scope) published prior to year 2000 is available on BIS Portal.

11.5 The BIS management has taken a policy decision to withdraw all those Indian Standards which are no more required by the industry / trade in view of present day scenario. The committee may examine the Standards given in the POW in the light of latest technological development and technology/ industrial trend world over as well as their application to the Indian industries and consider for their revision / amendment / withdrawal, if required.
As per the policy of BIS, the Indian Standards, which have completing five years since their last Publication/reaffirmation, are to be reviewed by the concerned sectional committee for their reaffirmation for a further period of five years, if the standard is still required.

11.6 The Indian Standards which are mentioned in **ANNEX 4**.
Reply is awaited

The committee may please note.

ITEM 12 DATE AND PLACE OF NEXT MEETING

ITEM 13 ANY OTHER BUSINESS.

ANNEX 1

(Item No 2.2)

Composition of Sectional Committee

S.no	Organization	Member Name
1.	In Individual Capacity	Lt Gen Sunil Kant
2.	3m India Limited, Bengaluru	Shri Kulveen Singh Bali
3.		Kavitha Kulkarni
4.		Dr. Prabha Hegde
5.	All India Institute Of Medical Sciences, New Delhi	Dr. Manju Nath Maruthi Pol
6.	Asia Pacific Medical Technology Association (Apacmed), Gurugram	Shri R. Ashok Kumar
7.		Sh. Parveen Jain
8.		Shreya Bansal
9.	Association Of Indian Medical Device Industry, New Delhi	Shri Rajiv Nath
10.		Shri Praveen Kumar Sharma
11.	B. Braun Medical India Private Limited, New Delhi	Dr. Anmol Kumar Ray
12.		Shri Arihant Jain
13.	Becton Dickinson India Private Limited, Gurugram	Shri Neeraj Sharma
14.		Sudhakar Mairpady
15.		Shri Prashanth Prabhakar
16.		Shri Dev Chopra
17.	Central Drugs Standard Control Organization, New Delhi	Dr. Ravi Kant Sharma
18.		Dr. V. G. Somani
19.	Dental Council Of India, New Delhi	Dr. Sanjay Tewari
20.		Dr. R.K. Tiwari
21.	Directorate General Armed Forces Medical Service, New Delhi	Col. Gaurav Kumar
22.	Dr Ram Manohar Lohia Hospital, New Delhi	Dr.Yashvant Singh
23.		Dr. Mohd Abu Masud Ansari
24.	E.I. Dupont India Private Limited, Gurugram	Shri. Vishnu Shankar Vyas
25.		Shri Srinivas S Cherukupalli
26.	Esic Dental College And Hospital, Delhi	Dr Dhirendra Srivastava
27.		Dr. Jitin Kharbanda
28.		Dr. Mansi Atri
29.	Employees State Insurance Corporation (Esic), New Delhi	Dr. S.K.Jain Dr Kayam Singh
30.		Dr. A.K.Agarwal R.K. Sharma
31.	Ganga Ram Hospital, New Delhi	Dr. Jyoti Randhawa

32.		Dr. Tarun Mittal
33.	Guru Teg Bahadur Hospital, New Delhi	Dr. Bharat B. Sagar
34.	Hcl, Noida	Shri Makesh Ramalingam
35.	Haffkine Institute For Training, Research & Testing, Mumbai	Dr. Shashikant Vaidya
36.		Dr Sandesha Pashte
37.	Hindustan Syringes And Medical Devices Limited, Ballabhgarh, Faridabad	Sh. Pradeep Sareen
38.	Indian Institute Of Technology Delhi, New Delhi	Shri Deepak Joshi
39.	Indian Institute Of Technology Kanpur, Kanpur	Dr J. Bera Chemistry
40.	Indian Medical Association, New Delhi	Dr R. N. Tandon
41.		Dr V. K. Monga
42.		Dr. Jayesh M. Lele
43.		Dr Sahajanand Prasad Singh
44.	Indian Pharmacopoeia Commission, Ghaziabad	Dr Anil Kumar Teotia
45.		Dr Manoj Kumar Pandey
46.	Iscon Surgicals Limited, Jodhpur	Shri Narendra Kumar Jain
47.		Shri Deepak Singhavi
48.	Johnson And Johnson Private Limited, Mumbai	Shri Shiv Kumar Hurdale
49.		Sh. Aaditya Vats
50.		Ms. Aishwarya Nair
51.	Kalam Institute Of Health Technology, Vishakhapatnam	Shri Dilip Kumar Chekuri
52.		Dr Jitendar Sharma
53.	Kanam Latex India Private Limited, Kottayam	Ravi Abraham
54.	Lady Irwin College, New Delhi	Dr Bhawana Chanana
55.		Dr Sheetal Chopra
56.	Maulana Azad Medical College, New Delhi	Dr. Deepak Ghuliani
57.		Anurag Mishra
58.	Microtrol Sterilisation Services Private Limited, Mumbai	Bansidhar S. Dhurandhar
59.		Manoj Mishra
60.		Shri Ranjeet V. Kalia
61.	Midmark (India) Private Limited, Mumbai	Shri Ashish M Deokar
62.		Mrs. Sarannya Jayakumar
63.	Ministry Of Commerce And Industry, Department Of Commerce, New Delhi	Ms. Sangeeta Saxena
64.	Ministry Of Railways, New Delhi	Dr. A.V.S.K Prasad
65.		Dr.Atul Sharma
66.	Nat Steel Equipment Private Limited, Mumbai	Shri Deepak Chalke
67.		Shri Jayant Pahapale
68.	Office Of Development Commissioner (Msme), New Delhi	Shri Kanwalinder Singh Sodhi
69.		Shri G.S.Bhatia
70.		Shri G.S.Bhatia
71.	Paramount Surgimed Limited, New Delhi	Shri Shaily Grover

72.		Shri Abhay Kumar
73.	Post Graduate Institute of Medical Education and Research, Chandigarh	Dr. Navneet
74.		Dr. Shweta Talati
75.	Precision Electronics Instruments and Components, Mumbai	Shri Sital D. Shah
76.	Ram Manohar Lohia Hospital, New Delhi	Dr. A. K. Goila
77.	Safdarjung Hospital, New Delhi	Dr. Vimal Bhandari
78.	Shriram Institute for Industrial Research, Delhi	Dr. Ajeet Aggarwal
79.		Ajeet Kr. Agarwal
80.		Dr. Binu Bhat
81.	Stryker India Private Limited, Gurugram	Mr. Shivkumar Hurdale
82.	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.
83.		V M Shajahan

ANNEX 2

(Item No 7)

Comment from Kanam Latex

Sub: **REVISION IN IS:15354 TO GIVE MORE PROTECTION AND LESS COST.**

IS:15354, pays more attention to glove thickness and less importance to barrier properties like pin holes. The primary intended use of medical examination glove is to prevent cross contamination between healthcare worker and patient. Hence shouldn't IS:15354 pay more attention to pinholes and follow what EN 455-1,2,3,4 has (**AQL 1.5** as gainst **AQL 2.5** which is very relaxed allowance).

IS:15354 asks for minimum thickness of gloves to be 0.08mm. at palm and finger and goes on to specify that if the glove is textured the thickness should be increased to 0.11mm. i.e. plus 0.03 mm. This is very arbitry as textures vary from mild to very high texture. Thickness is important to the extend that the glove should not tear, while donning. To prevent manufacturer from making very thin glove, EN specifies, that **force at breack using 3mm. dumbell cut piece should be 6 Newton**. Manufacturers have been able to offer Nitrile Gloves with average weight in size medium of 3.5 g. to meet this required physcial properties and AQL of 1.5 for pinholes. In case of latex examination gloves, the minimum weight that will be required to meet force at break of 6 newton will be around 5g. (size Medium).

Basically the specification should look at intended use, how long is the product used, and cost of the product. Normally a medical exam glove is used for very short time - may be one minute to 5 minutes or at most 10 minutes as GMP, asks that a medical practitioner should not use gloves to handle more than one patient.

BIS 15354 increases the cost of product, by asking minimum thickness of 0.11mm. when it is not needed and reduces the safety by allowing higher AQL for barrier properties to AQL 2.5 which is a paradox. This to our opinion is wrong, especially for medical examination gloves made from synthetic latex like Nitrile, Neoprene etc. Have users of medical examination gloves (Hospitals/Labs/Dentists been consulted). Do they prefer a thicker glove (more cost) but with AQL of 2.5 for pinholes or would they prefer a slightly thinner glove (3.5g. as against 4.5g.) and with less tolerance to barrier properties like maximum allowed pinholes of 1.5

National and International standards fix the **minimum** requirements. If a user wants a thicker glove as per his intended use, he will ask for 4.5g. or 5 g. or 5.5.g. or even 7 g. (as in case of high risk gloves) and he will be willing to pay more.

Do hope BIS will re-consider IS:15354, and align it will present intended use and takes into account, higher degree of safety (reduce pinholes) and less cost, reduce consumption of raw materials and chemicals used - (nitrile latex).

ANNEX 3

(Item No 10.3)

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	Not adopted
9.	ISO 3826-2:2008	Plastics collapsible containers for human blood and blood components — Part 2: Graphical symbols for use on labels and instruction leaflets	Adopted

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 — Single-use containers for the collection of specimens from humans other than blood	Not adopted
16.	ISO 8362-1:2018	Injection containers and accessories — Part 1: Injection vials made of glass tubing	Under development
17.	ISO 8362-2:2015	Injection containers and accessories — Part 2: Closures for injection vials	Under development
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	Under development
21.	ISO 8362-5:2016	Injection containers and accessories — Part 5: Freeze drying closures for injection vials	Not adopted
22.	ISO 8362-6:2010	Injection containers and accessories — Part 6: Caps made of aluminium-plastics combinations for injection vials	Not adopted
23.	ISO 8362-7:2006	Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part	Not adopted
24.	ISO 8536-1:2011	Infusion equipment for medical use — Part 1: Infusion glass bottles	Adopted
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	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles —	Not adopted

	1:2022	Amendment 1	
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
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	Under development
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	Not adopted
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
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 11418-7:2016	Containers and accessories for pharmaceutical preparations — Part 7: Screw-neck vials made of glass tubing for liquid dosage forms	Adopted
67.	ISO 13926-1:2018	Pen systems — Part 1: Glass cylinders for pen-injectors for medical use	Adopted
68.	ISO 13926-2:2017	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	Under development
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
74.	ISO 15747:2018	Plastic containers for intravenous injections	Not adopted
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 24166-2:2022	Snap-on bottles for metering pumps — Part 2: Moulded glass	Not adopted
83.	ISO 24166-3:2022	Snap-on bottles for metering pumps — Part 3: Plastic	Not adopted
84.	ISO 28620:2020	Medical devices — Non-electrically driven portable infusion devices	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	Not adopted
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	Not adopted
6.	ISO 11137-1:2006/Amd 2:2018	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 2: Revision to 4.3.4 and 11.2	Not adopted
7.	ISO 11137-2:2013	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose	Adopted

8.	ISO 11137-2:2013/Amd 1:2022	Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose — Amendment 1	Not adopted
9.	ISO 11137-3:2017	Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control	Adopted
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
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 low-temperature 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	Not adopted
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	Not adopted
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 requirements	Under development
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	Not adopted
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	Not adopted
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:	Not adopted

		Bacterial endotoxin testing	
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	Not adopted
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	Not 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 washer-disinfectors 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 washer-disinfectors employing thermal disinfection for human waste containers	Adopted
47.	ISO 15883-4:2018	Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	Not adopted
48.	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	Not adopted
49.	ISO 15883-6:2011	Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment	Adopted
50.	ISO 15883-7:2016	Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment	Not adopted
51.	ISO/TS 16775:2021	Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2	Not 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	Not adopted
53.	ISO 17664-2:2021	Processing of health care products — Information to be provided by the	Not adopted

		medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices	
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	Under development
55.	ISO/TS 17665-2:2009	Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1	Not adopted
56.	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
57.	ISO 18362:2016	Manufacture of cell-based health care products — Control of microbial risks during processing	Not adopted
58.	ISO 18362:2016/Amd 1:2022	Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1	Not adopted
59.	ISO 18472:2018	Sterilization of health care products — Biological and chemical indicators — Test equipment	Not adopted
60.	ISO/TS 19930:2017	Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6	Adopted
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 —	Not adopted

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

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	Not 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 single-use catheters — Part 1: General requirements	Adopted
10.	ISO 10555-1:2013/Amd 1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements — Amendment 1	Not adopted
11.	ISO 10555-3:2013	Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters	Adopted
12.	ISO 10555-4:2013	Intravascular catheters — Sterile and single-use catheters — Part 4: Balloon dilatation catheters	Adopted

13.	ISO 10555-5:2013	Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters	Adopted
14.	ISO 10555-6:2015	Intravascular catheters — Sterile and single-use catheters — Part 6: Subcutaneous implanted ports	Not adopted
15.	ISO 10555-6:2015/Amd 1:2019	Intravascular catheters — Sterile and single-use catheters — Part 6: Subcutaneous implanted ports — Amendment 1	Not adopted
16.	ISO 11070:2014	Sterile single-use intravascular introducers, dilators and guidewires	Not adopted
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 over-needle peripheral intravascular catheters	Not adopted
26.	ISO/TR 19244:2014	Guidance on transition periods for standards developed by ISO/TC 84 — Devices for administration of medicinal products and catheters	Not adopted
27.	ISO 20069:2019	Guidance for assessment and evaluation of changes to drug delivery systems	Not adopted
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	Under development
31.	ISO 20697:2018	Sterile drainage catheters and accessory devices for single use	Not adopted
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	Not adopted
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	Not adopted

ANNEX 4

(Item No 11.6)

Indian Standards for Committee

S.No	IS/ISO No.	Title	Due Date	Status
1.	IS 10985 : 1984 Reviewed In : 2017	Specification for needle, acupuncture	Dec 05, 2022	Review document circulated to members
2.	IS 11043 : 1984 Reviewed In : 2017	Specification for needle, epidural	Dec 05, 2022	Review document circulated to members
3.	IS 11400 : 1985 Reviewed In : 2017	Specification for hypodermic syringes, interchangeable type for general purposes	Dec 05, 2022	Review document circulated to members
4.	IS 12050 : 1986 Reviewed In : 2017	Specification for sterile hypodermic syringes with needle attached for single use	Dec 05, 2022	Review document circulated to members
5.	IS 3237 (Part 1) : 1985 Reviewed In : 2017	Specification for special purpose syringes: Part 1 insulin syringes (Second Revision)	Dec 05, 2022	Review document circulated to members
6.	IS 3237 (Part 2) : 1985 ISO 594-2 Reviewed In : 2017	Specification for special purpose syringes: Part 2 tuberculin syringes (Second Revision)	Dec 06, 2022	Review document circulated to members
7.	IS 3237 (Part 3) : 1985 Reviewed In : 2017	Specification for special purpose syringes: Part 3 bcg syringes (Second Revision)	Dec 06, 2022	Review document circulated to members
8.	IS 3237 (Part 4) : 1986 Reviewed In : 2017	Specification for special purpose syringes: Part 4 vaccine syringe	Dec 06, 2022	Review document circulated to members
9.	IS 3237 (Part 5) : 1986 Reviewed In : 2017	Specification for special purpose syringes: Part 5 post operation care syringe (Second Revision)	Dec 06, 2022	Review document circulated to members
10.	IS 3237 (Part 6) : 1986 Reviewed In : 2017	Specification for special purpose syringes: Part 6 irrigation syringe	Dec 06, 2022	Review document circulated to members
11.	IS 3237 (Part 7) : 1986 Reviewed In : 2017	Specification for special purpose syringe: Part 7 forced feeding syringe	Dec 06, 2022	Review document circulated to members
12.	IS 3237 (Part 8) : 1986	Specification for special purpose syringes: Part 8	Dec 06, 2022	Review document circulated to

	Reviewed In : 2017	angiography syringe		members
13.	IS 6208 : 1971 Reviewed In : 2017	Specification for spoons, plastics, measuring, medicine	Dec 05, 2022	Review document circulated to members
14.	IS 7171 : 1974 Reviewed In : 2017	Specification for drip counter with filter	Dec 05, 2022	Review document circulated to members
15.	IS 7523 : 1974 Reviewed In : 2017	Specification for rubber catheter (Urinary)	Dec 05, 2022	Review document circulated to members