MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT
BUREAU OF INDIAN STANDARDS

AGENDA

Meeting	***Day & Date***	***Time***
10th Meeting of Hospital Surgical Equipment and Disposal Sectional Committee	Monday, 15th May 2023	11:00 am
Meeting link: https://bisindia.webex.com/bisindia/j.php?MTID=m1db24dc9efa481fd2abe1e6d77d15eb3 **Meeting Id:** 2515 113 6930 Password : Mhd@12		

Chairperson: Maj 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 9th meeting of Hospital Equipment and Surgical Disposal Sectional Committee MHD 12 held on 14/12/2022 via WebEx Platform were circulated vide MHD 12/A2.9 dated 24.04.2023. 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 theatres 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.

- New Co-option received from Dr. Sunney Sebastian Maliekal as a **Rubber Technologist.**

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- Non-active members to be withdrawn and young professionals who can contribute in the working of the committee may be co-opted.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

ITEM 3 DRAFT INDIAN STANDARDS UNDER PRINT

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

S. No.	***Doc No.***	***Title***
1	MHD 12 (19174)/ ISO 21387:2020	Sterilization of medical devices Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release
2	MHD 12 (19164) /ISO 11139: 2018	Sterilization of health care products Vocabulary of terms used in sterilization and related equipment and process standards
3	MHD 12 (19225)/ ISO/TS 16775:2021	Packaging for terminally sterilized medical devices Guidance on the application of ISO 11607-1 and ISO 11607- 2
4	MHD 12(19169)/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 106
5	MHD 12(20818)/ISO 8362-3:2001	Injection containers and accessories Part 3: Aluminum caps for injection vials
6	MHD 12(16276)/ ISO 8362-1:2018	Injection containers and accessories Part 1 Injection vials made of glass tubing (Fourth Revision)
7	MHD 12(20819)/ ISO 9187-2:2010	Injection equipment for medical use Part 2: One-point-cut OPC ampoules
8	MHD 12(20822)/ ISO 10555-6:2015	Intravascular catheters Sterile and single-use catheters Part 6: Subcutaneous implanted ports
9	MHD 12(16286)/ ISO 13926-3:2019	Pen systems Part 3 Seals for pen-injectors for medical use
10	MHD 12 (17148)/ISO 11193-1:2020	Single-use medical examination gloves Part 1 Specification for gloves made from rubber latex or rubber solution Second Revision

11	MHD 12(19189)/ ISO 20696:2018	Sterile urethral catheters for single use
12	MHD 12(19192)/ 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 Amendment - 1
13	MHD 12 (19177)/ ISO /TS 22421	Sterilization of health care products Common requirements for sterilizers for terminal sterilization of medical devices in health care facilities
14	MHD 12(20823)/ISO /TS11137-4:2020	Sterilization of health care products Radiation Part 4: Guidance on process control
15	MHD 12 (00490)/ ISO 11140-1:2014	Sterilization of health care products — Chemical indicators — Part 1: General requirements

The committee may please note.

ITEM 5 DRAFT INDIAN STANDARDS FOR FINALIZATION

There are no draft Indian standard for finalization.

The committee may please finalize the documents for publication.

ITEM 6 DOCUMENT FOR APPROVAL FOR WIDE CIRCULATION

S.No	ISO Title	Remarks
1	Plastics collapsible containers for human blood and blood components Part 1 Conventional containers First Revision	3826-1 (an amendment has been issued by ISO)
2	Intravascular catheters - Sterile and single - Use catheters: Part 1 general requirements	10555-1 (an amendment has been issued by ISO)
3	Prefilled syringes Part 4 Glass barrels for injectables and sterilized subassembled syringes ready for filling	11040-4 (an amendment has been issued by ISO)
4	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	11135 (an amendment has been issued by ISO)
5	Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137-1 (an amendment has been issued by ISO)
6	Sterilization of health care products - Radiation: Part 2 establishing the sterilization dose	11137-2 (an amendment has been issued by ISO)
7	Sterilization of health care products Microbiological methods Part 1: Determination of a population of microorganisms on products	11737-1 (an amendment has been issued by ISO)

The committee may please note.

ITEM 7 COMMENTS ON PUBLISHED STANDARDS

There are no comments received on published standards

The committee may note.

ITEM 8 NEW SUBJECTS

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

The committee may please propose any new subjects that can be taken up.

ITEM 9 TECHNICAL ISSUES

There are no any technical issues.

The committee may note

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 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	I9SO/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	1) Dr. Ravi Kant Sharma, CDSCO, New Delhi

		components	

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 disposal 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 No.	Title	Reaffirmation Month and Year
1	IS 10654 : 2018 ISO 7864 : 2016 Ster	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 maintenanceand of sterilizers	July 2023
4	IS 13422 : 1992	Disposable surgical rubber gloves specification	June 2023
5	IS 7350 : 1974	Specification for needles, spinal	September 2023
6	IS 7387 : 1974	Needle, Biopsy, Liver, Silverman's Pattern	August, 2023
7	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
8	IS 15354 (Part 1) : 2018 ISO 11193-1 : 2008	Single - Use medical examination gloves: Part 1 specification for gloves made from rubber latex or rubber solution (First Revision)	December 2023
9	IS 15354 (Part 2) : 2018 ISO 11193-2 : 2006	Single - Use medical examination gloves: Part 2 specification for gloves made from poly (Vinyl Chloride) (First Revision)	December 2023

As per the decision of the last meeting, the review analysis of the following mentioned standards was circulated among the committee members for their comments/views.

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.

The committee may please note.

ITEM 12 DATE AND PLACE OF NEXT MEETING

ITEM 13 ANY OTHER BUSINESS .

Annex 1

S.No.	Organization	Member Name
1	IN INDIVIDUAL CAPACITY	MAJ GEN SUNIL KANT, VSM
2	3M India Limited, Bengaluru	Shri Kulveen Singh Bali
3	3M India Limited, Bengaluru	SHRI KULVEEN SINGH BALI
4	3M India Limited, Bengaluru	Kavitha Kulkarni
5	3M India Limited, Bengaluru	Dr. Prabha Hegde
6	All India Institute of Medical Sciences, New Delhi	Prof. Anita Dhar
7	All India Institute of Medical Sciences, New Delhi	Dr. Manju Nath Maruthi Pol
8	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shri R. Ashok Kumar
9	Asia Pacific Medical Technology Association (APACMed), Gurugram	Sh. Parveen Jain
10	Asia Pacific Medical Technology Association (APACMed), Gurugram	Shreya Bansal
11	Association of Indian Medical Device Industry, New Delhi	Shri Rajiv Nath
12	Association of Indian Medical Device Industry, New Delhi	Shri Praveen Kumar Sharma
13	Becton Dickinson India Private Limited, Gurugram	Shri Neeraj Sharma
14	Becton Dickinson India Private Limited, Gurugram	Sudhakar Mairpady
15	Borosil Glass Works Limited, Mumbai	Shri Shrikant Gangan
16	Boston Scientific India Private Limited, Gurugram	Shri Prashanth Prabhakar
17	Boston Scientific India Private Limited, Gurugram	Shri Dev Chopra
18	Central Drugs Standard Control Organization, New Delhi	Dr. Ravi Kant Sharma
19	Central Drugs Standard Control Organization, New Delhi	Dr. V. G. Somani
20	Dental Council of India, New Delhi	Dr. Sanjay Tewari
21	Dental Council of India, New Delhi	Dr. R.K. TIWARI
22	Directorate General Armed Forces Medical Service, New Delhi	COL. GAURAV KUMAR
23	Directorate General Armed Forces Medical Service, New Delhi	Col Sameer Kumar
24	Dr Ram Manohar Lohia Hospital, New Delhi	DR.YASHVANT SINGH

25	Dr Ram Manohar Lohia Hospital, New Delhi	DR YASHVANT SINGH
26	Dr Ram Manohar Lohia Hospital, New Delhi	Dr. Mohd Abu Masud Ansari
27	E.I. DuPont India Private Limited, Gurugram	SHRI. VISHNU SHANKAR VYAS
28	E.I. DuPont India Private Limited, Gurugram	SHRI SRINIVAS S CHERUKUPALLI
29	ESIC Dental College and Hospital, Delhi	Dr Dhirendra Srivastava
30	ESIC Dental College and Hospital, Delhi	DR. JITIN KHARBANDA
31	ESIC Dental College and Hospital, Delhi	DR. MANSI ATRI
32	Employees State Insurance Corporation (ESIC), New Delhi	DR. S.K.JAIN DR KAYAM SINGH
33	Employees State Insurance Corporation (ESIC), New Delhi	DR. A.K.AGARWAL R.K. SHARMA
34	Ganga Ram Hospital, New Delhi	Dr. Jyoti Randhawa
35	Ganga Ram Hospital, New Delhi	Dr. Tarun Mittal
36	Guru Teg Bahadur Hospital, New Delhi	DR. BHARAT B. SAGAR
37	HCL, Noida	Shri Makesh Ramalingam
38	Haffkine Institute For Training, Research & Testing, Mumbai	Dr. Shashikant Vaidya
39	Haffkine Institute For Training, Research & Testing, Mumbai	Dr Sandesha Pashte
40	Hindustan Syringes and Medical Devices Limited, Ballabhgarh, Faridabad	SH. PRADEEP SAREEN
41	Indian Institute of Technology Delhi, New Delhi	Shri Deepak Joshi
42	Indian Institute of Technology Delhi, New Delhi	SANDEEP K.JHA
43	Indian Institute of Technology Kanpur, Kanpur	Dr J. Bera Chemistry
44	Indian Medical Association, New Delhi	Dr R. N. Tandon
45	Indian Medical Association, New Delhi	Dr V. K. Monga
46	Indian Medical Association, New Delhi	Dr. Jayesh M. Lele
47	Indian Medical Association, New Delhi	Dr Sahajanand Prasad Singh
48	Indian Pharmacopoeia Commission, Ghaziabad	Dr Anil kumar Teotia
49	Indian Pharmacopoeia Commission, Ghaziabad	Dr Manoj Kumar Pandey
50	Indian Pharmacopoeia Commission, Ghaziabad	Dr. Anil Kumar Teotia
51	Iscon Surgicals Limited, Jodhpur	Shri Narendra Kumar Jain
52	Iscon Surgicals Limited, Jodhpur	Shri Deepak Singhavi
53	Johnson and Johnson Private Limited, Mumbai	Shri Shiv Kumar Hurdale
54	Johnson and Johnson Private Limited, Mumbai	Sh. Aaditya Vats
55	Johnson and Johnson Private Limited, Mumbai	Ms. Aishwarya Nair
56	KOB Medical Textiles Private Limited, Tiruppur	Shri S. Kumar Subramanian

57	KOB Medical Textiles Private Limited, Tiruppur	Shri A. Shanmugavasan
58	Kalam Institute of Health Technology, Vishakhapatnam	Shri Dilip Kumar Chekuri
59	Kalam Institute of Health Technology, Vishakhapatnam	Dr Jitendar Sharma
60	Kalam Institute of Health Technology, Vishakhapatnam	Manoj G
61	Kalam Institute of Health Technology, Vishakhapatnam	Shri Kiran Kumar.P
62	Kalam Institute of Health Technology, Vishakhapatnam	Smt. A . PRIYADARSHINI
63	Kanam Latex India Private Limited, Kottayam	Ravi Abraham
64	Lady Irwin College, New Delhi	Dr Bhawana Chanana
65	Lady Irwin College, New Delhi	Dr Sheetal Chopra
66	Maulana Azad Medical College, New Delhi	DR. DEEPAK GHULIANI
67	Maulana Azad Medical College, New Delhi	ANURAG MISHRA
68	Microtrol Sterilisation Services Private Limited, Mumbai	Bansidhar S. Dhurandhar
69	Microtrol Sterilisation Services Private Limited, Mumbai	Manoj Mishra
70	Microtrol Sterilisation Services Private Limited, Mumbai	Shri RANJEET V. KALIA
71	Midmark (India) Private Limited, Mumbai	SHRI ASHISH M DEOKAR
72	Midmark (India) Private Limited, Mumbai	MRS. SARANNYA JAYAKUMAR
73	Ministry of Commerce and Industry, Department of Commerce, New Delhi	Ms. Sangeeta Saxena
74	Ministry of Railways, New Delhi	Dr. A.V.S.K Prasad
75	Ministry of Railways, New Delhi	Dr.Atul Sharma
76	NAT Steel Equipment Private Limited, Mumbai	SHRI DEEPAK CHALKE
77	NAT Steel Equipment Private Limited, Mumbai	SHRI JAYANT PAHAPALE
78	Office of Development Commissioner (MSME), New Delhi	SHRI KANWALINDER SINGH SODHI
79	Office of Development Commissioner (MSME), New Delhi	Shri G.S.Bhatia
80	Office of Development Commissioner (SSI), New Delhi	Shri G.S.Bhatia(transferred)
81	Paramount Surgimed Limited, New Delhi	SHRI SHAILY GROVER
82	Paramount Surgimed Limited, New Delhi	SHRI ABHAY KUMAR
83	Paramount Surgimed Limited, New Delhi	SHRI ABHAY KUMAR
84	Post Graduate Institute of Medical Education and Research, Chandigarh	DR. NAVNEET DHALIWAL
85	Post Graduate Institute of Medical Education and Research, Chandigarh	DR. SHWETA TALATI
86	Post Graduate Institute of Medical Education and Research, Chandigarh	DR.NAVNEET DHALIWAL
87	Post Graduate Institute of Medical Education and Research, Chandigarh	DR.SHWETA TALATI

88	Precision Electronics Instruments and Components, Mumbai	SHRI SITAL D. SHAH
89	Ram Manohar Lohia Hospital, New Delhi	DR. A. K. GOILA
90	Safdarjung Hospital, New Delhi	DR. VIMAL BHANDARI
91	Shriram Institute for Industrial Research, Delhi	Dr. Ajeet Aggarwal
92	Shriram Institute for Industrial Research, Delhi	Ajeet kr. Agarwal
93	Shriram Institute for Industrial Research, Delhi	DR. BINU BHAT
94	Stryker India Private Limited, Gurugram	Mr. Shivkumar Hurdale
95	Terumo Penpol Private Limited, Thiruvananthapuram	Shri Manoj A.
96	Terumo Penpol Private Limited, Thiruvananthapuram	V M Shajahan
97	Vardhman Mahavir Medical College and Safdarjung Hospital, New Delhi	Dr. Vimal Bhandhari

ANNEX 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	
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	2023 amed
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:	Adopted

		Aphaeresis blood bag systems with integrated features	
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	Adopted
16	ISO 8362-1:2018	Injection containers and accessories — Part 1: Injection vials made of glass tubing	Adopted
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	Adopted
21	ISO 8362-5:2016	Injection containers and accessories — Part 5: Freeze drying closures for injection vials	Not adopted
22	ISO 8362-7:2006	Injection containers and accessories — Part 7: Injection caps made of aluminium-plastics combinations without overlapping plastics part	Not adopted
23	ISO 8536-1:2011	Infusion equipment for medical use — Part 1: Infusion glass bottles	adopted
24	ISO 8536-2:2023	Infusion equipment for medical use — Part 2: Closures for infusion bottles	Not adopted
25	ISO 8536-3:2009	Infusion equipment for medical use — Part 3: Aluminium caps for infusion bottles	Not adopted
26	ISO 8536-4:2019	Infusion equipment for medical use — Part 4: Infusion sets for single use, gravity feed	Adopted
27	ISO 8536-5:2004	Infusion equipment for medical use — Part 5: Burette infusion sets for single use, gravity feed	Not adopted
28	ISO 8536-6:2016	Infusion equipment for medical use — Part 6: Freeze drying closures for infusion bottles	Not adopted
29	ISO 8536-7:2009	Infusion equipment for medical use — Part 7: Caps made of aluminium-plastics combinations for infusion bottles	Not adopted

30	ISO 8536-8:2015	Infusion equipment for medical use — Part 8: Infusion sets for single use with pressure infusion apparatus	Not adopted
31	ISO 8536-9:2015	Infusion equipment for medical use — Part 9: Fluid lines for single use with pressure infusion equipment	Not adopted
32	ISO 8536-10:2015	Infusion equipment for medical use — Part 10: Accessories for fluid lines for single use with pressure infusion equipment	Not adopted
33	ISO 8536-11:2015	Infusion equipment for medical use — Part 11: Infusion filters for single use with pressure infusion equipment	Not adopted
34	ISO 8536-12:2021	Infusion equipment for medical use — Part 12: Check valves for single use	Not adopted
35	ISO 8536-13:2016	Infusion equipment for medical use — Part 13: Graduated flow regulators for single use with fluid contact	Not adopted
36	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
37	ISO 8536-15:2022	Infusion equipment for medical use — Part 15: Light-protective infusion sets for single use	Not adopted
38	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
39	ISO 8871-1:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 1: Extractables in aqueous autoclavates	Not adopted
40	ISO 8871-2:2020	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 2: Identification and characterization	Not adopted
41	ISO 8871-3:2003	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 3: Determination of released-particle count	Not adopted
42	ISO 8871-4:2006	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 4: Biological requirements and test methods	Not adopted
43	ISO 8871-5:2016	Elastomeric parts for parenterals and for devices for pharmaceutical use — Part 5: Functional requirements and testing	Not adopted
44	ISO 8872:2022	Aluminium caps and aluminium/plastic caps for infusion bottles and injection vials — General requirements and test methods	Not adopted
45	ISO 9187-1:2010	Injection equipment for medical use — Part 1: Ampoules for injectables	Adopted
46	ISO 9187-2:2010	Injection equipment for medical use — Part 2: One-point-cut (OPC) ampoules	Under development
47	ISO 11040-1:2015	Prefilled syringes — Part 1: Glass cylinders for dental local anaesthetic cartridges	Adopted

48	ISO 11040-2:2011	Prefilled syringes — Part 2: Plunger stoppers for dental local anaesthetic cartridges	Adopted
49	ISO 11040-3:2012	Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges	Adopted
50	ISO 11040-4:2015	Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Adopted
51	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
52	ISO 11040-5:2012	Prefilled syringes — Part 5: Plunger stoppers for injectables	Adopted
53	ISO 11040-6:2019	Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling	Not adopted
54	ISO 11040-7:2015	Prefilled syringes — Part 7: Packaging systems for sterilized subassembled syringes ready for filling	Not adopted
55	ISO 11040-8:2016	Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes	Not adopted
56	ISO 11418-1:2016	Containers and accessories for pharmaceutical preparations — Part 1: Drop-dispensing glass bottles	Adopted
57	ISO 11418-2:2016	Containers and accessories for pharmaceutical preparations — Part 2: Screw-neck glass bottles for syrups	Adopted
58	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
59	ISO 11418-3:2016	Containers and accessories for pharmaceutical preparations — Part 3: Screw-neck glass bottles (veral) for solid and liquid dosage forms	Adopted
60	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
61	ISO 11418-4:2005	Containers and accessories for pharmaceutical preparations — Part 4: Tablet glass bottles	Not adopted
62	ISO 11418-5:2015	Containers and accessories for pharmaceutical preparations — Part 5: Dropper assemblies	Adopted
63	ISO 11418-7:2016	Containers and accessories for pharmaceutical preparations — Part 7: Screw-neck vials made of glass tubing for liquid dosage forms	Adopted
64	ISO 13926-1:2018	Pen systems — Part 1: Glass cylinders for pen-injectors for medical use	Adopted

65	ISO 13926-2:2017	Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use	Adopted
66	ISO 13926-3:2019	Pen systems — Part 3: Seals for pen-injectors for medical use	Under development
67	ISO 15010:1998	Disposable hanging devices for transfusion and infusion bottles — Requirements and test methods	Not adopted
68	ISO 15137:2005	Self-adhesive hanging devices for infusion bottles and injection vials — Requirements and test methods	Not adopted
69	ISO 15375:2010	Medical infusion bottles — Suspension devices for multiple use — Requirements and test methods	Not adopted
70	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
71	ISO 15747:2018	Plastic containers for intravenous injections	Not adopted
72	ISO 15759:2005	Medical infusion equipment — Plastics caps with inserted elastomeric liner for containers manufactured by the blow-fill-seal (BFS) process	Not adopted
73	ISO/TR 19727:2017	Medical devices — Pump tube spallation test — General procedure	Not adopted
74	ISO 21881:2019	Sterile packaged ready for filling glass cartridges	Not adopted
75	ISO 21882:2019	Sterile packaged ready for filling glass vials	Not adopted
76	ISO 22413:2021	Transfer sets for pharmaceutical preparations — Requirements and test methods	Not adopted
77	ISO/TS 23128:2019	Medical devices — Transfusion set and blood bag compatibility test method	Not adopted
78	ISO 24166-1:2022	Snap-on bottles for metering pumps — Part 1: Tubular glass	Not adopted
79	ISO 24166-2:2022	Snap-on bottles for metering pumps — Part 2: Moulded glass	Not adopted
80	ISO 24166-3:2022	Snap-on bottles for metering pumps — Part 3: Plastic	Not adopted
81	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	Adopted

		dosimetric aspects of development, validation and routine control	
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	Not 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 — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	Adopted
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 13004:2022	Sterilization of health care products — Radiation — Substantiation of selected sterilization dose: Method VDmaxSD	Not adopted
31	ISO 13408-1:2008	Aseptic processing of health care products — Part 1: General requirements	Adopted
32	ISO 13408-1:2008/Amd 1:2013	Aseptic processing of health care products — Part 1: General requirements — Amendment 1	Adopted
33	ISO 13408-2:2018	Aseptic processing of health care products — Part 2: Sterilizing filtration	Adopted
34	ISO 13408-3:2006	Aseptic processing of health care products — Part 3: Lyophilization	Not adopted
35	ISO 13408-4:2005	Aseptic processing of health care products — Part 4: Clean-in-place technologies	Not adopted
36	ISO 13408-5:2006	Aseptic processing of health care products — Part 5: Sterilization in place	Not adopted
37	ISO 13408-6:2021	Aseptic processing of health care products — Part 6: Isolator systems	Not adopted
38	ISO 13408-7:2012	Aseptic processing of health care products — Part 7: Alternative processes for medical devices and combination products	Not adopted

39	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
40	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
41	ISO 15882:2008	Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results	Under development
42	ISO 15883-1:2006	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	Adopted
43	ISO 15883-1:2006/Amd 1:2014	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests — Amendment 1	Not adopted
44	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
45	ISO 15883-3:2006	Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	Adopted
46	ISO 15883-4:2018	Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	Not adopted
47	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	Not adopted
48	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	Not adopted
49	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

50	ISO/TS 16775:2021	Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2	Not adopted
51	ISO 17664-1:2021	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices	Adopted
52	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	Not adopted
53	ISO 17665-1:2006	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	Adopted
54	ISO/TS 17665-2:2009	Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1	Not adopted
55	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
56	ISO 18362:2016	Manufacture of cell-based health care products — Control of microbial risks during processing	Not adopted
57	ISO 18362:2016/Amd 1:2022	Manufacture of cell-based health care products — Control of microbial risks during processing — Amendment 1	Not adopted
58	ISO 18472:2018	Sterilization of health care products — Biological and chemical indicators — Test equipment	Not adopted
59	ISO/TS 19930:2017	Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6	Under development
60	ISO 20857:2010	Sterilization of health care products — Dry heat — Requirements for the development, validation and routine control of a sterilization process for medical devices	Adopted
61	ISO/TS 21387:2020	Sterilization of medical devices — Guidance on the requirements for the validation and routine processing of ethylene oxide sterilization processes using parametric release	Adopted

62	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
63	ISO 22441:2022	Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices	Not adopted
64	ISO/TS 22456:2021	Sterilization of healthcare products — Microbiological methods— Guidance on conducting bioburden determinations and tests of sterility for biologics and tissue-based products	Not adopted
65	ISO 25424:2018	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices	Not adopted
66	ISO 25424:2018/Amd 1:2022	Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices — Amendment 1	Not adopted

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 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	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 verification — Requirements and test methods	Not adopted
29	ISO 20695:2020	Enteral feeding systems — Design and testing	Not adopted
30	ISO 20696:2018	Sterile urethral catheters for single use	Adopted
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	Adopted
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	Adopted
35	ISO 23907-2:2019	Sharps injury protection — Requirements and test methods — Part 2: Reusable sharps containers	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	Adopted