PRODUCT MANUAL FOR

Sterilization of Health Care Products Common Requirements for Sterilizers for Terminal Sterilization of Medical Devices in Health Care Facilities as per IS 18287: 2023

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता हैI

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards (Conformity Assessment) Regulations,2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	**मानक संख्या** **IS No.**	:	IS 18287: 2023
	शीर्षक **Title**	:	Sterilization of Health Care Products Common Requirements for Sterilizers for Terminal Sterilization of Medical Devices in Health Care Facilities
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	NA
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 machine
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**

5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	All possible tests as specified IS 18287: 2023
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 18287: 2023*** with the following scope:

Name of the product	Sterilization of Health Care Products Common Requirements for Sterilizers for Terminal Sterilization of Medical Devices in Health Care Facilities
Model	
Type of Chamber	Cylindrical horizontal or cylindrical vertical chambers / Rectangular parallelepiped chambers / Other configurations
Internal Dimension of the sterilizer chamber	(Refer 5.2.1.1 of IS 18287)
Usable Sterilizer Chamber Space	(Refer 5.2.1.2 of IS 18287)
Pressure vessels	With / Without
Maximum operating pressure and hydrostatic pressure	(if applicable)
Connection to IT environment	With / Without
Sterilization Process (agent)	
No. of doors (Means of access to the chamber)	One door / Two doors
Ratings	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V Frequency …. Hz, Rated current …..A Input Power …..VA (or) …..W
Nature of Supply	ac (or) dc
EMC Classification based on operating areas or vicinity of other sensitive equipment	As per IEC 61326-1

ANNEX -A

Grouping Guidelines

1. Manufacturer shall submit the declaration for each of the parameters as specified in scope of the licence (as per Sl. No. 6 above) of each model of 'Sterilizers' they intend to cover in the scope of licence.

2. For considering Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'Sterilizer' is to be tested.

3. During the operation of the Licence, BO shall ensure that all the model(s) covered in the Scope of the Licence are tested in rotation to the extent possible.

Note 1: Firm shall submit the Technical description as per Cl. 11.6 of IS 18287 for each of the Model of Sterilizer.

Note 2: Firm shall submit the dimensions and drawing of the Sterilizer and its chamber.

Note 3: Firm shall declare the accessories or sterilizing agent provided alongwith the Sterilizer.

ANNEX- B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Accessible Parts 5.9.2	Test Finger with accessibility test apparatus
3.	Humidity preconditioning treatment, 5.7	Conditioning chamber with temperature and humidity chamber
4.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
5.	Earth Leakage Current, 8.7.4.5, Touch Current, 8.7.4.6, Patient Leakage Current, 8.7.4.7	Figure 13 to Figure 18, Leakage Current Tester, metal foil, Test Pin as per Figure 8 or a particular tool as specified by manufacturer
6.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, Multimeter/Earth Resistance Tester
7.	Dielectric Strength, 8.8.3	High Voltage Tester
8.	Creepage Distances and Air Clearances 8.9	Vernier Caliper, Filler Gauge

Note 1: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 18287: 2023 for each model in the scope of license.

Note 2: The Technical File and Risk Management File shall be maintained by the licensee till the End of Life for each model.

ANNEX C
SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1. It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1.

1.3.2 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. **ENSURING COMPLIANCE THROUGH TESTING**- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 **Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1)**, where different tests given in the specification shall be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 **TEST RECORDS**- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

2.5.1 TECHNICAL FILE- Licencee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ inclusion/ surveillance.

2.5.1.1 The Technical File shall be maintained till the End of Life of the model.

2.5.1.2 Licencee shall declare the frequency of periodic review of Technical file to BIS and record of review shall be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.5.1.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

2.5.1.4 The technical file shall consist of the following documents:

- Technical description of the product (as per Cl. 11.6 of IS 18287)
- Product Manual and/ or Instructions for use (as per Cl. 11.5 of IS 18287);
- Instructions for repair/ service for the product/ components, if required;
- Frequency of periodic repair/ service for the product/ components, if required;
- Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc with descriptions and explanations needed for the understanding of these drawings;
- A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
- Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
- Copies of conformity assessment documentation for critical product components and accessories;

2.5.2 RISK MANAGEMENT FILE- The licencee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS 18287: 2023. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

2.5.2.1 The Risk Management File shall be maintained till the End of Life of each model.

2.5.2.2 Licencee shall declare the frequency of periodic review of Risk Management File to BIS and record of review shall be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Technical File.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Pulse Oximeter Equipment provided always that the material so marked conforms to each requirement of the specification.

3.1 Marking and labeling shall be done as per Cl. 11.3 and Cl. 11.4 of IS 18287: 2023 respectively.

3.2. **Additional Marking requirements**: The material shall also be marked with the following additional requirement on each product and packaging:

a) "For BIS certification details please visit www.bis.gov.in"

3.3. All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

4. HYGIENIC CONDITIONS (if applicable) – NA.

5. REJECTION - Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act,2016.

TABLE-1

(1)				(2)	(3)		
Test Details				Test Equipment requirement R: Required (or) S: Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
4	**General**						
4.1	Product definition	4.1.1 4.1.2	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
4.3	Calibration	4.3.1 4.3.2	IS 18287	R	One		
5	**Equipment design and construction**						
5.1	**Safety and Security**						
	Marking and documentation	5	IEC 61010-2-040	R	Each Sterilizer		
	Protection against electric shock	6	IEC 61010-2-040	S			
	Protection against mechanical HAZARDS and against HAZARDS related to mechanical functions	7	IEC 61010-2-040	S			
	Resistance to mechanical stresses	8	IEC 61010-2-040	S	One	Once in every six months for each model manufactured during that period	
	Protection against the spread of fire	9	IEC 61010-2-040	S	One		
	Equipment temperature limits and resistance to heat	10	IEC 61010-2-040	S	One		
	Protection against HAZARDS from fluids and solid foreign objects	11	IEC 61010-2-040	S	One		

	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	12	IEC 61010-2-040	S	One	Once in every six months for each model manufactured during that period	
	Protection against liberated gases, substances, explosion and implosion	13	IEC 61010-2-040	S	One		
	Components and subassemblies	14	IEC 61010-2-040	S	Each consignment	No further testing is required if accompanied with Test Certificate or covered in Risk Management file	
	Protection by interlocks	15	IEC 61010-2-040	S	One	Once in every six months for each model manufactured during that period	
	HAZARDS resulting from application	16	IEC 61010-2-040	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
	RISK assessment	17	IEC 61010-2-040	R	One		
5.1.3	Protection against unauthorized access	5.1.3	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
5.2	**Chamber**						
5.2.1	Dimensions	5.2.1.1 5.2.1.2	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
5.2.2	Doors	5.2.2	IS 18287	R	Each Steriliser		
5.2.3	Chamber Integrity	5.2.3	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
5.2.4	Pressure Vessels	5.2.4	IS 18287	R			
5.2.5	Uniformity of Conditions	5.2.5	IS 18287	R			
5.2.6	Ancillary equipment and components	5.2.6.1 5.2.6.2	IS 18287	R			

5.3	Materials	5.3	IS 18287	R	Each Consignment	No further testing if accompanied with Test Certificate or covered in Risk Management file	
5.4	Interlocks	5.4.1	IS 18287	R	Each Steriliser		
		5.4.3					
		5.4.2			One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
		5.4.4					
		5.4.5					
5.5	Test connections	5.5.1	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
		5.5.2					
		5.5.3					
		5.5.4					
		5.5.5			Each Steriliser		
5.6	Vibration	5.6	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
5.7	User Interface	5.7.1	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
		5.7.2					
		5.7.3					
		5.7.4					
		5.7.5			Each Steriliser		
		5.7.5					
		5.7.6					
6	**Indicating, monitoring, controlling and recording**						
6.1	General	6.1	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
6.2	Automatic Control	6.2.1	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
		6.2.2					
		6.2.3					
		6.2.4					
		6.2.5					

		6.2.6 6.2.7					
6.3	**Control and monitoring system**						
	Control and monitoring system	6.3.1 6.3.2 6.3.3 6.3.4 6.3.5 6.3.6	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
6.4	**Failure**						
6.4.1	General	6.4.1.1 6.4.1.2	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
6.4.2	Fault	6.4.2.1 6.4.2.2 6.4.2.4	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
		6.4.2.3 6.4.2.5			Each Sterilizer		
6.4.3	Power Failure	6.4.2	IS 18287	R	Each Sterilizer		
6.4.4	Other Failures	6.4.4.1 6.4.4.2 6.4.4.3 6.4.4.4	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
6.5	**Instrumentation**						
	Instrumentation	6.5.1 6.5.2 6.5.3 6.5.4 6.5.5	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
6.6	**Indicating Devices**						

	Indicating devices	6.6.1 to 6.6.5	IS 18287	R	Each Sterilizer		Testing and assessment of the product to be done as specified in the technical documentation
6.7	**Recorders**						
	Recorders	6.7.1 6.7.2 6.7.3 6.7.4 6.7.5 6.7.6	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
					Each Sterilizer		
7	**Services and local environment**						
7.1	General	7.1.1 to 7.1.3	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
7.2	Sterilizing agent and sterilant	7.2	IS 18287	R			
7.3	Electric Supply	7.3	IS 18287	R			
7.4	Water	7.4.1 7.4.2	IS 18287	R			
7.5	Steam	7.5	IS 18287	R			
7.6	Vacuum	7.6	IS 18287	R			
7.7	Drains	7.7	IS 18287	R			
7.8	Lighting	7.8	IS 18287	R			
7.9	Compressed Air	7.9	IS 18287	R			
7.10	Air and Inert gas	7.10	IS 18287	R			
7.11	Ventilation	7.11	IS 18287	R			
8	**Emissions**						
8.1	**Electromagnetic emissions**		IEC 61326-1	S	One	Once in every three years for each model	

						manufactured during that period	
8.2	Noise	8.2.1 to 8.2.4	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
8.3	Exhaust emissions	8.3.1 8.3.2	IS 18287	R			
8.4	Heat emissions	8.4.1 8.4.2	IS 18287	R	Each Sterilizer		
					One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
9	**Test Instrumentation**						
	Test instrumentations	9.1 9.2 9.3 9.4 9.5 9.6	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
					Each Sterilizer		
10	**Performance and assessment**						
10.3	Attainment of condition	10.3	IS 18287	R	One	Once in every six months for each model manufactured during that period	Testing and assessment of the product to be done as specified in the technical documentation
10.4	Microbial Performance	Annex D	IS0 14937	R			
10.5	Pressure Change	10.5	IS 18287	R			
11	**Information supplied by the Manufacturer**						
11.1	General	11.1 to 11.6	IS 18287	R			