उत्पाद मैन्युअल

आई एस 3119: 1978 के अनुसार

तप्त वायु स्टेरलाइजंर

दस्तावेज़ संख्या - पी एम/आई एस 3119/1/जनवरी 2021

भारतीय मानक ब्यूरो की स्कीम-I (अनुरूपता मूलयाांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिर्शिता की सुसंगतता सुनिश्चित करने के लिए सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसी द्वारा संदर्भ सामग्री के रूप में उपयोग किया जाएगा। बीआईएस प्रमाणीकरण लाइसेंस/ प्रमाणपत्र प्राप्त करने के इच्छुक भावी आवेदकों द्वारा भी इस दस्तावेज़ का उपयोग किया जा सकता है ।

PRODUCT MANUAL FOR
HOT AIR STERILIZERS
ACCORDING to IS 3119: 1978

Document No.- PM/IS 3119/1/January 2021

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence 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 licence/certificate.

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1.	**Product**	:	IS 3119: 1978
	Title	:	Hot Air Sterilizers
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per Cl.4 of IS 3119
b)	**Grouping guidelines**	:	For considering GoL/ CSoL, Sterilizer of highest load rating shall be tested to cover all load ratings up to and including the load rating tested.
c)	**Sample Size**	:	One Sterilizer
3.	**List of Test Equipment**	:	Please refer ANNEX – A
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX – B
5.	**Possible tests in a day:**	:	All test except Test for Reproducibility of Temperature setting as per Cl. 9.2.9 and Temperature Overshoot test as per Cl. 9.2.10.
6.	**Scope of the Licence:**	:	
	"Licence is granted to use Standard Mark as per IS 3119: 1978 with the following scope:		
	Name of the product	Hot Air Sterilizers	
	Load rating (kW)		

ANNEX A

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sl No.	Tests used in with clause reference	Test Equipment(s)
1.	Protection Against Electric Shock (Cl. 6.1)	Test probe with multimeter
2.	Electric Insulation (Cl. 6.3)	Metal foil, Leakage Current Tester, Isolation transformer, HV test supply, Network as per relevant fig. of IS 302-1
3.	Stability (Cl. 6.4)	Inclined plane, masses, force gauges, test probe similar to test probe B of IS 1401 with circular stop face 50 mm Ø, Stop plate, test rod
4.	Mechanical Strength (Cl. 6.5)	Spring hammer, Hardened steel pin, Force gauges
5.	Supply Connections (Cl. 6.6)	Flexing test apparatus, Cord anchorage force & torque tester, Cold chamber
6.	Terminals (Cl. 6.7)	Torque screwdriver
7.	Earthing (Cl. 6.8)	Earth continuity tester
8.	Screws and Connections (Cl. 6.9)	Torque gauge
9.	Resistance to Rusting (Cl. 6.10)	Humidity Chamber with Temp and Humidity Controller Measuring Cylinder 500 ml Ammonium Chloride, Carbon Tetrachloride, Distilled Water
10.	Heating up Time (Cl. 7.1)	Thermometer, Stop watch.
11.	Thermal performance (Cl. 7.2, Cl. 9.2.5 to 9.2.10)	Long stem thermometer of mercury-in glass type, thermocouple/thermistor, Stop watch.
12.	High Voltage test (Cl. 9.2).	HV tester.

The above list is indicative only and may not be treated as exhaustive.

ANNEX B

Scheme of Inspection and Testing

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING – As per the requirement of IS 3119.

4. CONTROL UNIT - All Sterilizers manufactured in a week shall constitute a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

6. REJECTIONS – 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 Required (R) or Sub-contracting permitted (S)	Levels of Control		
Cl.	Requirement	Test Method			No. of samples	Frequency	Remarks
		Clause	Reference				
4	Material	4.1	IS 3119	S	one	Each consignment	Please see Note 1
5	**Construction**						
	General	5.1	IS 3119	-	Each Sterilizer		-
	Cabinet	5.2	IS 3119	-	Each Sterilizer		-
	Heating Element	5.3					-
	Wiring and Components	5.4					-
	Thermostat	5.5					-
	Thermometer	5.6					-
6	**General and Safety Requirement**						
	Temperature Limit	6.2	IS 3119	R	One	Every 15th control unit	Please see Note 4
	Stability	6.4		R	One	Each control unit	Please see Note 2
	Mechanical Strength	6.5		S	One	Every 5th control unit	Please see Note 4
	Supply Connections	6.6		R	One	Each control unit	Please see Note 2
	Terminals	6.7					

	Earthing	6.8	IS 3119	R	Each Sterilizer		-
	Screws and Connections	6.9			One	Each control unit	Please see Note 2
	Resistance to Rusting	6.10					Please see Note 3
7	**Performance Requirements**						
7.1	Heating up Time	7.1	IS 3119	R	One	Every 5th control unit	Please see Note 4
7.2	Thermal Performance	7.2, 9.2.3					
	Routine Test						
	Visual Examination and Inspection	9.2.1	IS 3119	-	Each Sterilizer		-
	Protection against Electric Shock	Table 1		R			-
	High Voltage	Table 1					-
	Insulation resistance	9.2.2 & Table 1					-
	Leakage Current	Table 1					-
	Earthing connection	Table 1					-
	Type Test						
	Performance test for thermostats	9.2.4 & Table 1	IS 3119	S	Three	Each lot	Please see Note 4
	Temperature Variation test	9.2.5 & Table 1		R	One	Every 5th control unit	
	Temperature Differential test	9.2.6 & Table 1					
	Temperature Drift test	9.2.7 & Table 1					
	Test for time of temperature recovery	9.2.8 & Table 1					

	Test for reproducibility of temperature setting	9.2.9 & Table 1	IS 3119	R	One	Every 5th control unit	Please see Note 4
	Temperature overshoot test	9.2.10 & Table 1					

Note-1: The Component parts used in the assembly and construction shall conform to the relevant Indian Standards wherever they exist. Raw materials which are covered under mandatory certification of BIS shall be ISI marked and received along with manufacturer's test certificate. For other materials, no further testing is required if received with test certificate or ISI marked.

Note-2: In case of failure, all the sterilizers in the control unit shall be tested and those not passing shall be rejected. Twice the number of samples shall be tested in the subsequent control units for these requirements till five consecutive control units pass, the original frequency may then be restored.

Note-3: In case of failure twice the original number of samples from the control unit shall be tested and the control unit shall be accepted only if there is no failure.

Note-4: In case of failure the marking shall be suspended. Necessary corrective actions shall be taken. Marking and frequency of testing shall only be resumed when five sterilizers from the improved production show conformity to the requirements.

Note-5: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-6: Levels of control given in column 3 are recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.