



**PRODUCT MANUAL FOR
STERILIZERS, BOWL AND UTENSILS
(PEDAL TYPE)
ACCORDING TO IS 5035: 1969**

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.

1.	Product	:	IS 5035: 1969
	Title	:	Sterilizers, Bowl and Utensils (Pedal Type)
	No. of Amendments	:	Nil
2.	Sampling Guidelines:		
a)	Raw material	:	As per Clause 5, 8.4 and 9.2 of IS 5035
b)	Grouping guidelines	:	Please refer ANNEX A
c)	Sample Size	:	One Sterilizer
3.	List of Test Equipment	:	Please refer ANNEX B
4.	Scheme of Inspection and Testing	:	Please refer ANNEX C
5.	Possible tests in a day	:	All Tests
6.	Scope of the Licence:		
	“Licence is granted to use Standard Mark as per IS 5035: 1969 with the following scope:		
	Name of the product	Sterilizers, Bowl and Utensils (Pedal Type)	
	Sizes	Size 1/ 2/ 3/ 4/ 5/ 6/	
	Method of Operation	Electric Operation (Loading in kW)/ Direct Steam Operation/ Gas Operation/ Kerosene Operation.	

ANNEX A

Grouping Guidelines

1. For the purpose of GoL/ CSoL, classification as given below shall be considered:
 - Method of operation:
 - Electric operation
 - Direct steam operation
 - Gas operation
 - Kerosene operation
2. Considering the above, Sterilizer of any size from each method of operation shall be tested separately to cover all sizes from that particular method of operation.
3. For Electrically operated Sterilizers, sample of highest load rating shall be tested to cover all load ratings upto and including the load rating tested.
4. The Firm shall declare the varieties of Sterilizers they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.
5. During the operation of the Licence, BO shall ensure that all the varieties covered in the Licence are tested in rotation, to the extent possible.

ANNEX B**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
1.	Dimension, Cl. 4	Measuring Tape
2.	Material thickness, Cl. 5.1	Vernier Caliper, Micrometer
3.	Construction, Cl. 6	Radius Gauge, Bevel Protractor, Distributed load as per Cl. 6.2.1, measuring tape.
4.	Functional Requirement, Cl. 7	Thermometer
5.	Electric Operation, Cl. 8.1	Mega Ohm meter, High Voltage Tester, Stop watch.
6.	Direct Steam Operation, Cl. 8.2.2	Pressure test setup with pressure gauges.

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

ANNEX C

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 5035.

4. 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. 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 R: required (or) S: Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Methods			No. of Sample	Frequency	Remarks
		Clause	Reference				
3	Design	3.1	IS 5035	-	Each Sterilizer	-	-
4	Dimensions	4.1 & Table 1		R	Each Sterilizer	-	-
5	Materials	5.1		S	Every consignment received		
6	Construction	6.1, 6.2, 6.3		R	Each Sterilizer	-	-
7	Functional Requirements	7.1		R	Each Sterilizer	-	-
8.1	Electric Operation	8.1		R	Each Sterilizer	-	-
8.2	Direct Steam Operation	8.2		R	Each Sterilizer	-	-
8.3	Gas Operation	8.3		R	Each Sterilizer	-	-
8.4	Kerosene Operation	8.4		R	Each Sterilizer	-	Oil Pressure Stove/ Oil Pressure Heater shall be ISI marked
9	Finish	9.1, 9.3, 9.4		-	Each Sterilizer	-	-
		9.2	S	One	Each Consignment	No further testing is required if accompanied with Test Certificate.	

Note- 1: The materials which are covered under the mandatory certification of BIS shall be ISI marked and received along with manufacturers test certificate. For other materials, no further testing is required if accompanied with Test Certificate or ISI marked.

Note-2: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-3: Levels of control given in column 3 are only 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.