



**PRODUCT MANUAL FOR
STEAM STERILIZERS - HORIZONTAL CYLINDRICAL AND
HORIZONTAL RECTANGULAR STEAM STERILIZERS, PRESSURE
TYPE (FOR HOSPITAL AND PHARMACEUTICAL USE)
ACCORDING TO IS 3829 (Part 1):1999**

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 3829 (Part 1): 1999
	Title	:	Horizontal Cylindrical and Horizontal Rectangular Steam Sterilizers, Pressure Type (for Hospital and Pharmaceutical use)
	No. of Amendments	:	Nil
2.	Sampling Guidelines:		
a)	Raw material	:	As per Clause 6 of IS 3829 (Part 1): 1999
b)	Grouping guidelines	:	Please refer ANNEX - A
c)	Sample Size	:	1 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	:	Please refer ANNEX - D

ANNEX A

Grouping Guidelines

1. Steam Sterilizers as per IS 3829 (Part 1): 1999 are classified based on the following:
 - (a) Type of Control
 - Non-automatic
 - Automatic Process Control
 - Pulsing Type
 - (b) Shape and Size
 - Horizontal Cylindrical – Dimensions as per Table 1 of IS 3829 (Pt 1)
 - Horizontal Square or Horizontal Rectangular - Dimensions as per Table 2 of IS 3829 (Pt 1)
 - (c) Type of Door
 - Single Door
 - Double Door
 - (d) Source of Steam Supply
 - Directly from Steam Boiler
 - From built-in Steam Generator
 - Electric Heating
 - Kerosene Stove Heating
 - Gas Heating
 - Combination Heating
 - Direct Steam/Electric
 - Direct Steam/Kerosene Stove
 - Direct Steam/Gas
 - Electric/Kerosene Stove
 - Electric/Gas
2. Considering the above, the guidelines given below shall be followed for GoL/CSoL:
 - Sample of any shape and size for each type of control and each design depending upon the source of steam supply shall be tested to cover all shapes and sizes for that particular type of control and design.
 - For Sterilizers designed to operate by means of built-in Steam Generator, each type of heating arrangement (Electric/Stove/Gas/Combination) shall be tested separately to cover that particular variety.

- For Sterilizer with combination heating, each type of combination shall be tested separately to cover that particular type.
 - If Sterilizer with double door is tested, Sterilizer with single door for the corresponding variety may also be covered.
3. 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.
 4. During the operation of license, it shall be ensured that all varieties covered in the license 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	Size Cl. 5.2	a) Measuring Tape b) Linear Measuring Scale
2	Shell Cl.7.2	a) Linear Measuring Scale b) Measuring Tape c) Vernier Caliper d) Outside Micrometer e) Height Gauge
3.	Door (Clause 7.3)	Coating thickness Gauge
4.	Locking Device (Clause 7.3.1)	Pressure gauge
5.	Fittings Cl 8.1	a) Measuring Tape b) Pressure Gauge c) Thermometer d) Stop Watch
6.	Hydrostatic test Cl. 9	a) Hydrostatic testing Station with pressure gauge b). Stop Watch
7.	Direct Steam Operation Cl 10.2	a) Pressure gauge
8.	Design (Clause 4) Size, (Clause 5.2) Electric Heating (Clause 10.4)	a) Micro meter b) Vernier Calliper c) Steel scale d) Measuring Tape e) Compound Gauge f) Thermometer g) AC Three Phase Energy Measurement h) (Voltage, Current, Wattage, frequency) i) High Voltage Test Earth Terminal Tester j) Insulation Tester k) Milli Ammeter l) Temperature Indicator

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 equipments.

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

3. LABELLING AND MARKING – As per Cl. 12 of IS 3829 (Pt 1).

3.1 Each Sterilizer shall be accompanied by an operating manual as per Cl. 13 of IS 3829 (Pt 1).

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.

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

5. 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 Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
6	Materials	6	IS 3829 (Pt 1)	S	One	Each Consignment	Please see Note 1
4	Design	4	IS 3829 (Pt 1)	R	Each Sterilizer		---
5	Shape & Size	5, Fig 1&2, Tables 1&2	IS 3829 (Pt 1)	R	Each Sterilizer		---
7	Construction	7	IS 3829 (Pt 1)	R	Each Sterilizer		---
8	Fittings	8	IS 3829 (Pt 1)	R	Each Sterilizer		---
9	Hydrostatic test	9.1&9.2	IS 3829 (Pt 1)	R	Each Sterilizer		---
10	Methods of steam supply to sterilizer	10.1 to 10.8	IS 3829 (Pt 1)	R	Each Sterilizer		---
11	Accessories (if provided)	11	IS 3829 (Pt 1)	R	Each Sterilizer		---

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

ANNEX D

Scope of Licence

“Licence is granted to use Standard Mark as per IS 3829 (Part 1):1999 with the following scope:	
Name of the product	Steam Sterilizers, Pressure Type (for Hospital and Pharmaceutical use)
Type of Control	
Source of Steam Supply	
Any other aspect required as per the Standard	Single Door/ Double Door