



**PRODUCT MANUAL FOR
STEAM STERILIZERS - HORIZONTAL CYLINDRICAL HIGH-SPEED
SEAM STERILIZERS, PRESSURE TYPE
ACCORDING TO IS 3829 (Part 2):1978**

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 2): 1978
	Title	:	Horizontal Cylindrical High-Speed Steam Sterilizers, Pressure Type
	No. of Amendments	:	4
2.	Sampling Guidelines:		
a)	Raw material	:	As per Clause 5 of IS 3829 (Part 2): 1978
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. The following parameter shall be considered for grouping of Steam Sterilizers as per IS 3829 (Part 2): 1978:
 - Type of Control
 - Non-automatic
 - Automatic Process Control
2. Considering the above, sample from each type of control shall be tested to cover sterilizers of that particular type of control.
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	Design (Clause 3.3) Size, (Clause 4.2) Electric Heating (Clause 9.3)	a) Micro meter b) Vernier Caliper 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
2.	Door (Clause 6.3)	Coating thickness Gauge
3	Locking Device (Clause 6.3.1) Safety valve (Clause 7.1.3)	Pressure gauge
4	Fittings Cl 7.1	a) Measuring Tape b) Pressure Gauge c) Thermometer d) Stop Watch
5	Hydrostatic test Cl. 8	a) Hydrostatic testing Station with pressure gauge b). Stop Watch

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. 11 of IS 3829 (Pt 2).

3.1 Each Sterilizer shall be accompanied by an operating manual as per Cl. 12 of IS 3829 (Pt 2).

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				
5	Materials	5	IS 3829 (Pt 2)	S	One	Each Consignment	Please see Note 1
3	Design	3	IS 3829 (Pt 2)	R	Each Sterilizer		---
4	Shape & Size	4, Fig 1	IS 3829 (Pt 2)	R	Each Sterilizer		---
6	Construction	6	IS 3829 (Pt 2)	R	Each Sterilizer		---
7	Fittings	7	IS 3829 (Pt 2)	R	Each Sterilizer		---
8	Hydrostatic test	8.1 & 8.2	IS 3829 (Pt 2)	R	Each Sterilizer		---
9	Methods of steam supply to sterilizer	9.1 to 9.4	IS 3829 (Pt 2)	R	Each Sterilizer		---
10	Accessories (if provided)	10	IS 3829 (Pt 2)	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 2):1978 with the following scope:	
Name of the product	Horizontal Cylindrical High-Speed Steam Sterilizers, Pressure Type
Type of Control	