



PRODUCT MANUAL FOR CERVICAL COLLAR ACCORDING TO IS 11569: 1966

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 11569: 1966
	Title	:	Cervical Collar
	No. of Amendments	:	One
2.	Sampling Guidelines:		
a)	Raw material	:	As per Cl.2 of IS 11569: 1966
b)	Grouping guidelines	:	Please refer ANNEX – A
c)	Sample Size	:	One piece
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 11569: 1966 with the following scope:		
	Name of the product	Cervical Collar	
	Size	Large/ Medium/ Small	

ANNEX A

Grouping Guidelines

1. Cervical Collars as per IS 11569:1966 are classified based on the size as follows:
 - Large
 - Medium
 - Small
2. Sample of cervical collar of the highest size from the sizes intended to be covered in the licence shall be tested for all requirements to cover cervical collar of that size in the licence. However, if sample of Large size is tested, Medium and Small sizes may also be covered in the scope of licence. Similarly, if sample of Medium size is tested, Small size may also be covered in the scope of licence.
3. The Firm shall declare the varieties of various Cervical Collars 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 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.	Shape and Dimensions, Cl. 3, Fig 1	Steel Scale, Vernier Caliper, Micro Meter, measuring tape, weighing scale

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 the requirement of IS 11569:1966.

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				
2	Material	Cl. 2.1 to 2.6	IS 11569	S	One	Each consignment	No further testing is required if accompanied with test certificate or ISI marked.
3	Shape and Dimensions	Cl. 3, Fig 1	IS 11569	R	Each collar		Any collar not meeting the requirement shall not be marked and shall be rejected.
4	Workmanship and Finish	Cl.4.1, 4.2	IS 11569	R	Each collar		

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: 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.