उत्पाद मैन्युअल
आई एस 11569 : 2023 के अनुसार
सरवाइकल कॉलर - विशिष्टि (पहला पुनरीक्षण) के लिए
दस्तावेज़ संख्या – पीएम/आईएस 11569 /2/ सितम्बर 2023

भारतीय मानक ब्यूरो की स्कीम-X (अनुरूपता मूलयांकन) विनियम, 2018 के तहत यह उत्पाद मैन्युअल प्रमाणीकरण के प्रचालन में रीति और पारिशिता 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
Specification for Cervical Collar (First Revision)
ACCORDING TO IS 11569 : 2023
Document No - PM/IS 11569/2/September 2023

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-X 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.

भारतीय मानक ब्यूरो
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New Delhi – 110002

PRODUCT MANUAL FOR
CERVICAL COLLAR - SPECIFICATION
ACCORDING TO IS 11569: 2023

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 : 2023
	Title	:	Cervical Collar – Specification (First Revision)
	No. of Amendments	:	NIL
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per Cl.3 of IS 11569: 2023
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: 2023 with the following scope:		
	Name of the product		Cervical Collar - Specification
	Size		Large/ Medium/ Small

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ANNEX A

Grouping Guidelines

1. Cervical Collars as per IS 11569:2023 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 aretested 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. 4, 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 – The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each appliance and also on its packaging.

3.1 Marking and Labelling shall be as per the requirement of IS 11569 : 2023.

3.2 In addition, the licence no. CM/L-_____ and details of BIS website shall be marked at an appropriate place as follows: "For details of BIS certification please visit www.bis.gov.in".

4. CONTROL UNIT – For the purpose of this scheme, the entire quantity of Cervical Collars made from same machine in each shift from same consignment of raw materials shall be considered as one 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 R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
2	Material	Cl. 3.1 to 3.6	IS 11569	S	One	Each consignment	No further testing is required if accompanied with test certificate or ISI marked.
3	Shape and Dimensions	Cl. 4.1, Fig 1 Cl. 4.2	IS 11569	R	Each Control Unit		
4	Workmanship and Finish	Cl. 5.1, 5.2	IS 11569	R	Firm to have adequate in-process controls to check compliance of this parameter as per the tolerances given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity.		

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 hisown levels of control in column 3 with proper justification for approval by BO Head.