PRODUCT MANUAL FOR MODULAR LOWER LIMB ORTHOTIC COMPONENTS – STIRRUP PLATES ACCORDING TO IS 9471(PART 3):1980

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 9471 (Part 3):1980
	Title	:	Modular Lower Limb Orthotic Components – Stirrup plates
	No. of Amendments	:	3
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	As per clause 3 of IS 9471 (Part 3): 1980
b)	**Grouping guidelines**	:	Sample of each Size shall be tested to cover Stirrup plates of that particular Size in the scope of licence.
c)	**Sample Size**	:	One piece
3.	**List of Test Equipment**	:	Please refer ANNEX –A
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX –B
5.	**Possible tests in a day**	:	(i) Shape and Dimensions (ii) Workmanship and finish
6.	**Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS 9471(Part 3): 1980 with the following scope:		
	Name of the product		Modular Lower Limb Orthotic Components -Stirrup plates
	Sizes		Size 1/ Size 2/ Size 3

ANNEX A

List of Test Equipment

Major test equipment required to test as per the Indian Standard

Sr. No.	Test Equipment	Tests Used with clause reference
1	1. Dial/digital vernier caliper 2. Steel scale 3. Micrometer 4. Radius gauge 5. Bevel protractor	Dimensions – Cl 2
2	1. Distilled water 2. Glacial acetic acid 3. Diphenyl carbozide 4. Wetting agent (sulphonated alcohol type) 5. Concentrated HCl (relative density l-16) 6. Sodium hypochlorite (10-15 percent solution) 7. Hydrogen peroxide 8. Antimony trioxide 9. Cu disc 10. Heat insulated chamber	Workmanship and finish - Cl 5

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

ANNEX B

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 requirements of IS 9471 (Part 3).

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. CONTROL UNIT- All the stirrup plates of the same size manufactured from the same raw material in a day shall constitute a control unit.

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 Clause**	**Reference**		**No. of Sample**	**Frequency**	**Remarks**
2	Shape and Dimensions	2	IS 9471 (Part 3)	R	Each stirrup plate		Any stirrup plates not meeting the requirement shall not be marked and shall be rejected.
3	Material	3	IS 9471 (Part 3)	-	Each consignment		Material used in the manufacture of stirrup plate shall be ISI marked
4	Fabrication	4	IS 9471 (Part 3)	-	Two	Each control unit	If any sample fails, two more samples to be tested. Lot to be accepted only if both the samples pass.
5	Workmanship and Finish	5	IS 9471 (Part 3)	R	Each stirrup plate		Any stirrup plate not meeting the requirement shall not be marked and shall be rejected.

Note-1: 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 B.O. Head.