



**PRODUCT MANUAL FOR  
MODULAR LOWER LIMB ORTHOTIC COMPONENTS –  
ORTHOTIC JOINTS BARS, ANKLE AND KNEE (UPPER AND LOWER)  
ACCORDING TO IS 9471(PART 7):2000**

*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.	<b>Product</b>	:	IS 9471 (Part 7):2000
	<b>Title</b>	:	Modular Lower Limb Orthotic Components - Orthotic Joints Bars, Ankle and Knee (Upper and Lower)
	<b>No. of Amendments</b>	:	1
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	As per clause 5 of IS 9471 (Part 7): 2000
b)	<b>Grouping guidelines</b>	:	Sample from each Size and Type shall be tested to cover orthotic joint bars of that particular Size and Type in the scope of licence.
c)	<b>Sample Size</b>	:	One piece
3.	<b>List of Test Equipment</b>	:	Please refer ANNEX –A
4.	<b>Scheme of Inspection and Testing</b>	:	Please refer ANNEX –B
5.	<b>Possible tests in a day</b>	:	(i) Shape and Dimensions (ii) Workmanship and finish
6.	<b>Scope of the Licence:</b>		
	“Licence is granted to use Standard Mark as per IS 9471(Part 7): 2000 with the following scope:		
	Name of the product	Modular Lower Limb Orthotic Components - Orthotic Joint Bars	
	Type	Ankle Bar/ Knee Upper Bar/Knee Lower bar	
	Sizes	Size I/Size II/Size III	

**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 4
2	1. R – 15 mandrel 2. Angle protractor 3. Arrangement for bend test	Bend test - Cl 7

*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 7).

**4. CONTROL UNIT** - All the Joint Bars of the same size and type manufactured from the same raw material in a day shall constitute a 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.

**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**

<b>(1)</b>				<b>(2)</b>	<b>(3)</b>		
<b>Test Details</b>				<b>Test equipment requirement R: required (or) S: Sub-contracting permitted</b>	<b>Levels of Control</b>		
<b>Cl.</b>	<b>Requirement</b>	<b>Test Methods Clause</b>	<b>Reference</b>		<b>No. of Sample</b>	<b>Frequency</b>	<b>Remarks</b>
4	Shape and Dimensions	4.1- 4.2	IS 9471 (Part 7)	R	Each Joint bar		Any joint bar not meeting the requirement shall not be marked and shall be rejected.
5	Material	5.1	IS 9471 (Part 7)	S	Each consignment		Further testing of raw material is not necessary if it is accompanied with supplier's TC or ISI marked.
6	Workmanship and Finish	6.1 – 6.2	IS 9471 (Part 7)	R	Each Joint bar		Any joint bar not meeting the requirement shall not be marked and shall be rejected.
7	Bend Test	7.1	IS 9471 (Part 7)	R	2	Each Control Unit	If any sample fails, two more samples to be tested. Lot to be accepted only if both the samples pass.

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 B.O. Head.