



**PRODUCT MANUAL FOR  
MODULAR LOWER LIMB ORTHOTIC COMPONENTS –  
ORTHOTIC HIP JOINT (JOINT UNIT, HIP DROP LOCK)  
ACCORDING TO IS 9471(PART 6):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 6):2000
	<b>Title</b>	:	Modular Lower Limb Orthotic Components - Orthotic Hip Joint (Joint Unit, Hip Drop Lock)
	<b>No. of Amendments</b>	:	0
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	As per clause 4 of IS 9471 (Part 6): 2000
b)	<b>Grouping guidelines</b>	:	Sample of each Size shall be tested to cover orthotic hip joint of that particular Size 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 6): 2000 with the following scope:		
	Name of the product	Modular Lower Limb Orthotic Components - Orthotic Hip Joint (Joint Unit, Hip Drop Lock)	
	Sizes	Size I/ Size II/ Size III	

**ANNEX A****List of Test Equipment**

*Major test equipment required to test as per the Indian Standard*

<b>Sr. No.</b>	<b>Test Equipment</b>	<b>Tests Used with clause reference</b>
1	1. Dial/digital vernier caliper 2. Steel scale 3. Micrometer 4. Radius gauge 5. Bevel protractor	Dimensions – Cl 3
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 6).

**4. CONTROL UNIT** – All the Orthotic Hip Joints of the same size 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.

**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**

<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>
3	Shape and Dimensions	3.1 to 3.3	IS 9471 (Part 6)	R	Each Orthotic Hip Joint		Any hip joint not meeting the requirement shall not be marked and shall be rejected.
4	Material	4	IS 9471 (Part 6)	S	Each consignment		Material used in the manufacture of joint body upper and lock drop ring shall be ISI marked. For other materials, further testing is not necessary if it is accompanied with supplier's TC or ISI marked.
5	Workmanship and Finish	5, 5.1	IS 9471 (Part 6)	R	Each Orthotic Hip Joint		Any hip joint not meeting the requirement shall not be marked and shall be rejected.
6	Functional Requirement	6	IS 9471 (Part 6)	R	Each Orthotic Hip Joint		Any hip joint not meeting the requirement shall not be marked and shall be rejected.
7	Bend Test	7	IS 9471 (Part 6)	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.