



**आई एस 9471 (भाग 6) : 2024 -  
मॉड्यूलर लोअर लिम्ब ऑर्थोटिक  
घटक : भाग 6 –  
ऑर्थोटिक हिप जॉइंट  
(ज्वाइंट यूनिट, हिप ड्रॉप लॉक) के अनुसार  
उत्पाद मैनुअल**

**PRODUCT MANUAL FOR  
Modular Lower Limb Orthotic  
Components — Specification  
Part 6 Orthotic Hip Joint  
(Joint Unit, Hip Drop Lock)  
as per IS 9471 (Part 6): 2024**

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

*This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.*

|    |                                             |   |                                                                                                                     |
|----|---------------------------------------------|---|---------------------------------------------------------------------------------------------------------------------|
| 1. | मानक संख्या<br>IS No.                       | : | IS 9471 (Part 6): 2024                                                                                              |
|    | शीर्षक<br>Title                             | : | Modular Lower Limb Orthotic Components — Specification Part 6<br>Orthotic Hip Joint (Joint Unit, Hip Drop Lock)     |
|    | संशोधनों की संख्या<br>No. of amendments     | : | 01                                                                                                                  |
| 2. | नमूना दिशानिर्देश<br>Sampling Guidelines    |   |                                                                                                                     |
| a) | कच्चा माल<br>Raw material                   | : | As per Cl. 4 of IS 9471 (Part 6): 2024                                                                              |
| b) | समूहीकरण दिशानिर्देश<br>Grouping Guidelines | : | One Sample of each Size shall be tested to cover orthotic hip joint of that particular Size in the scope of licence |
| c) | नमूने का परिमाण<br>Sample Quantity          | : | One                                                                                                                 |
| d) | परीक्षण अनुरोध में घोषित                    | : | <ul style="list-style-type: none"> <li>Size</li> </ul>                                                              |

|                                                                                                         |                                                                        |                                                                                                                 |                        |
|---------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|------------------------|
|                                                                                                         | किए जाने वाले पैरामीटर<br>Parameters to be Declared<br>in Test Request |                                                                                                                 |                        |
|                                                                                                         |                                                                        |                                                                                                                 |                        |
| 3.                                                                                                      | परीक्षण उपकरणों की सूची<br>List of Test Equipment                      | :                                                                                                               | Please refer ANNEX – A |
|                                                                                                         |                                                                        |                                                                                                                 |                        |
| 4.                                                                                                      | निरीक्षण और परीक्षण की स्कीम<br>Scheme of Inspection and Testing       | :                                                                                                               | Please refer ANNEX – B |
| 5.                                                                                                      | एक दिन में संभावित परीक्षण<br>Possible tests in a day                  | :                                                                                                               | All tests              |
| 6.                                                                                                      | लाइसेंस का दायरा /Scope of the Licence:                                |                                                                                                                 |                        |
| *License is granted to use Standard Mark as per <i>IS 9471 (Part 6): 2024</i> with the following scope: |                                                                        |                                                                                                                 |                        |
| Name of the product                                                                                     |                                                                        | Modular Lower Limb Orthotic Components — Specification Part 6<br>Orthotic Hip Joint (Joint Unit, Hip Drop Lock) |                        |
| Size                                                                                                    |                                                                        | Size I / Size II / Size III                                                                                     |                        |

**ANNEX- A**  
**LIST OF TEST EQUIPMENTS**  
**(INDICATIVE LIST, FOR GUIDANCE ONLY)**

| <b>Sl. No.</b> | <b>Tests used in with Clause Reference</b>                  | <b>Test Equipment</b>                                                                                                                                                                                           |
|----------------|-------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1              | Dimensions – Cl 3 & Fig 1                                   | Dial/digital vernier caliper<br>Steel scale<br>Micrometer<br>Radius gauge<br>Bevel protractor                                                                                                                   |
| 2              | Zinc plating with Service Cond 1 (as per IS 1573) – Cl. 5.3 | Microscopic method (or) Magnetic method (or) BNF Jet test method with reagents (or) Strapping method<br>Stop watch<br>Antimony trioxide<br>HCL, Triholorethylene<br>Copper disc<br>Saltspray chamber with timer |
| 2              | Bend test - Cl 7                                            | R – 15 mandrel<br>Angle protractor<br>Arrangement for bend test                                                                                                                                                 |

**ANNEX B**  
**SCHEME OF INSPECTION AND TESTING**

**1. QUALITY ASSURANCE PLAN**

- 1.1. It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.
- 1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

**1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:**

- 1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: All the Orthotic Hip Joints of the same size manufactured in a day from same consignment of raw material shall constitute a control unit.
- 1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1.
- 1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.
- 1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

- 2. ENSURING COMPLIANCE THROUGH TESTING-** It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

- 2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as “R” or other tests which can be subcontracted as “S”. Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

- 2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as “R” in Column 2 of Table 1) is also optional.**

- 2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done

from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

**2.3 Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as “R” in Column 2 of Table 1),** where different tests given in the specification shall be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website [www.bis.gov.in](http://www.bis.gov.in). (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

**2.4 TEST RECORDS-** The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

**3. PACKING AND MARKING** - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each orthotic hip joint provided always that the joint so marked conforms to each requirement of the specification.

3.1 Marking on each Orthotic hip joint shall be done as per Cl. 8 of IS 9471 (Part 6): 2024

3.2 **Additional Marking requirements:** The packaging of the orthotic hip joint shall also be marked with the following additional requirement on it:

a) “For BIS certification details please visit [www.bis.gov.in](http://www.bis.gov.in)”

3.3 All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark.

**4. HYGIENIC CONDITIONS (if applicable) – NA.**

**5. REJECTION** - 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<br>R: required (or)<br>S:Sub-contracting permitted                                                                                                                                                       | Levels of Control |                   |                                                                                        |
| Cl.          | Requirement             | Test Methods      |                                         |                                                                                                                                                                                                                                     | No. of Sample     | Frequency         | Remarks                                                                                |
|              |                         | Clause            | Reference                               |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 4            | Materials               |                   |                                         |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 4.1          | Joint Upper Body        | 4.1               | IS 9471-6<br>&<br>IS 10774              | S                                                                                                                                                                                                                                   | One               | Each consignment  | No further testing is required if accompanied with the Test Certificate or ISI marked. |
| 4.2          | Joint hip lower         | 4.2               | IS 9471-6<br>&<br>IS 1079               |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 4.3          | Lock drop ring          | 4.3               | IS 9471-6<br>&<br>IS 10774              |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 4.4          | Screw                   | 4.4               | IS 9471-6<br>&<br>IS 9550               |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 4.5          | Nut                     | 4.5               | IS 9471-6<br>&<br>IS 9550 /<br>IS 10774 |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 5            | WORKMANSHIP AND FINISH  | 5.1<br>5.2<br>5.3 | IS 9471-6                               | 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 |                   |                   |                                                                                        |
| 6            | FUNCTIONAL REQUIREMENTS | 6                 | IS 9471-6                               |                                                                                                                                                                                                                                     |                   |                   |                                                                                        |
| 7            | Bend Test               | 7                 | IS 9471-6                               | R                                                                                                                                                                                                                                   | One               | Each Control Unit |                                                                                        |