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उत्पाद मैन्युअल
मॉडुलर लोअर लिंब के ओर्थोटिक घटक : भाग 7 –
ओर्थोटिक जोड़ बार्स, टखने और घुटने (ऊपरी और निचले)
आई एस 9471 (भाग 7) : 2024 के अनुसार

PRODUCT MANUAL FOR
MODULAR LOWER LIMB ORTHOTIC COMPONENTS –
PART 7 : ORTHOTIC JOINT BARS, ANKLE AND KNEE (UPPER AND LOWER)
ACCORDING TO IS 9471 (PART 7):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** **IS No.**	:	IS 9471 (Part 7) : 2024
	शीर्षक **Title**	:	Modular Lower Limb Orthotic Components : Part 7 – Orthotic Joint Bars, Ankle and Knee (Upper And Lower)
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	The material used for the manufacture of orthotic joint bars shall be aluminium alloy of designation 64423 W/T4 of IS 733 or any other equivalent material. Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/ Factory Surveillance
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	One 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)	**नमूने का परिमाण** **Sample Quantity**	:	One piece Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (incase of market surveillance, effort may be made to procure therequired quantity of product sample, as far as possible since raw material sample may not be available in market)
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer to Annex-A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer to Annex-B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	All test requirements as per IS 9471 (Part 7):2024 Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide readyreference regarding the tests which can be witnessed during the inspection in the factory by the officer/auditor.		
6.	**लाइसेंस का दायरा /Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS 9471 (Part 7):2024 with the following scope:		
	Name of the product		Modular Lower Limb Orthotic Components : Part 7 – Orthotic Joint Bars, Ankle and Knee (Upper And Lower)
	Type		Ankle Bar/ Knee Upper Bar/Knee Lower bar
	Sizes		Size I/Size II/Size III

ANNEX-A

List of Test Equipment

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr. No.	**Tests Used with clause reference**	**Test Equipment**
1	Dimensions – Cl 3	1. Dial/digital vernier caliper 2. Steel scale 3. Micrometer 4. Radius gauge 5. Bevel protractor
2	Bend test - Cl 7	1. R – 15 mandrel 2. Angle protractor 3. Arrangement for bend test

ANNEX C
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 theStandard 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 differenttests 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: All the Orthotic Joint bars, ankle and knee of the same type and size manufactured from the same raw material in a day shall constitute a control unit.

1.3.2 For the guidance of manufacturers, the recommended definition of control unit is : All the Ankle Joint Units of the same size and type manufactured from the same raw material in a day shall constitute a control unit.

1.3.3 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.4 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 requirementsof 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 housetesting 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.

2.3 For the guidance of manufacturers, Table 1 giving the recommended levels of control is givenbelow. 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 perIS/ISO/IEC 17025.

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

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

2.5 **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 testsgiven 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.

2.5.1 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. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.6 **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 clearly and indelibly marked on each orthotic joint bar, provided always that the product so marked conforms to all requirements of the specification.

3.3 Marking shall be done as per Clause 8 of IS 9471 (Part 7):2024.

3.4 **Additional Marking requirements**: Each joint bar/ its package shall also be marked with the following detail:

a) "For BIS certification details please visit www.bis.gov.in"

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

(ONLY FOR GUIDANCE PURPOSE)

(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**
5	Material of Joint Bar	5	IS 9471 (Part 6)/ IS 733	S	One	Each consignment	No further testing is required, if received with test certificate or ISI marked.
4	Shape and Dimensions	4	IS 9471 (Part 7)	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.		
6	Workmanship and Finish	6	IS 9471 (Part 7)	R			
7	Bend Test	7	IS 9471 (Part 7)	R	One	Each Control Unit	-