



**PRODUCT MANUAL FOR
MODULAR LOWER LIMB ORTHOTIC COMPONENTS –
JOINT UNIT, ANKLE
ACCORDING TO IS 9471(PART 4):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 4):1980 |
| | Title | : | Modular Lower Limb Orthotic Components - Joint unit, ankle |
| | No. of Amendments | : | 2 |
| 2. | Sampling Guidelines: | | |
| a) | Raw material | : | As per clause 4 of IS 9471 (Part 4): 1980 |
| b) | Grouping guidelines | : | Sample from each Size and Type shall be tested to cover Ankle Joint Unit of that particular Size and Type 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 4): 1980 with the following scope: | | |
| | Name of the product | Modular Lower Limb Orthotic Components -Joint unit, ankle | |
| | Type | Type1/ Type 2/ Type 3/ Type 4 | |
| | 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 3 |
| 2 | 1. Mandrel 2. Induction furnace 3. Acidified potassium iodide/starch solution 4. Dilute Hydrochloric acid 5. Iron accelerator 6. Potassium iodate 7. Tin accelerator 8. Oxygen 9. Ammoniacal Zinc Sulphate Solution 10. Hexachloroplatinic Acid, 11. Hydrochloric Acid -Hexachloroplatinic Acid 12. Standard Potassium Iodate Solution, 13. Starch-Iodide Solution 14. Hydrogen Sulphide Evolution Apparatus 15. Nitrogen 16. Copper Sulphate 17. Sulphuric acid 18. Orthophosphoric acid | 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 4).

4. CONTROL UNIT - 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.

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

| (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 |
| 3 | Shape and Dimensions | 3.1 to 3.3 | IS 9471 (Part 4) | R | Each joint unit | | Any joint unit not meeting the requirement shall not be marked and shall be rejected. |
| 4 | Material | 4.1 to 4.5 | IS 9471 (Part 4) | S | Each consignment | | Material used in the manufacture of male and female parts of the joint unit 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 | 5.1 to 5.4 | IS 9471 (Part 4) | R | Each joint unit | | Any joint unit not meeting the requirement shall not be marked and shall be rejected. |
| 6 | Heat treatment | 6 | IS 9471 (Part 4) | 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.