



**PRODUCT MANUAL
FOR
ARTIFICIAL LIMBS – SACH FOOT FOR
LOWER EXTREMITY PROSTHESES
ACCORDING TO IS 12644(Part 1) : 2003**

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.

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|----|--|--|--|
| 1. | Product | : | IS 12644(Part 1) : 2003 |
| | Title | : | Artificial Limbs – SACH For Lower Extremity Prostheses Part 1 Design and Dimensions |
| | No. of Amendments | : | Nil |
| 2. | Sampling Guidelines: | | |
| a) | Raw material | : | Not Applicable |
| b) | Grouping guidelines | : | Please refer ANNEX – A |
| c) | Sample Size | : | One piece |
| 3. | List of Test Equipment | : | Please refer ANNEX – B |
| 4. | Scheme of Inspection and Testing | : | Please refer ANNEX – C |
| 5. | Possible tests in a day : | | |
| | All tests. | | |
| 6. | Scope of the Licence : | | |
| | Licence is granted to use Standard Mark as per IS 12644(Part 1) : 2003 with the following scope: | | |
| | Name of the product | Artificial Limbs – SACH For Lower Extremity Prostheses | |
| | Type | Type a) / Type b) / Type c) | |
| | Sizes | | |

ANNEX A

1. SACH foot are classified as following as per IS 12644(Part 1) : 2003 :

| Type | Foot Sizes | Description |
|---------|------------|--|
| Type a) | 3 to 11 | SACH foot with internal heel laminated construction without toes |
| Type b) | 3 to 11 | SACH foot with internal heel moulded construction without toes |
| Type c) | 3 to 11 | SACH foot with internal heel moulded construction with toes |

2. Considering the above following samples shall be tested :
- One sample each of the smallest size and largest size of Type a) shall be tested to cover all sizes in that size-range for Type a) SACH foot.
 - One sample each of the smallest size and largest size of Type c) shall be tested to cover all sizes in that size-range for Type b) and Type c) SACH foot.
 - One sample each of the smallest size and largest size of Type b) shall be tested to cover all sizes in that size-range for Type b) SACH foot when Type c) SACH foot are not required.
3. The Firm shall declare the varieties of various SACH foot they intend to cover in the Licence. The Scope of Licence may be restricted based on the manufacturing and testing capabilities of the manufacturer.
4. During operation of the licence, BO shall ensure that all the varieties covered in the licence are tested in rotation to the extent possible.

ANNEX B**List of Test Equipment**

Major test equipment required to test as per the Indian Standard

| Sl. No. | Tests used in with Clause Reference | Test Equipment |
|---------|-------------------------------------|---|
| 1 | Shape and Design (Clause 7) | (i) Ball Point Micro Meter (ii) Corresponding sizes of shoes (iii) Inside Micro Meter (iv) Measuring Tape/Thread (v) Outside Micro Meter (vi) Vernier Calliper |

The above list is indicative only and may not be treated as exhaustive.

ANNEX C

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 requirement of IS 12664(Part 1) : 2003.

4. CONTROL UNIT – All SACH foos manufactured under similar conditions from the same consignment of raw material in a day or part thereof, shall constitute one 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. HYGIENIC CONDITIONS – Wherever applicable, hygienic conditions shall be complied in day to day production and quality control activities. Schedule for each activity for this purpose shall be displayed prominently in the factory premises and records of compliance shall be maintained.

7. 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 Method | | | No. of Sample | Frequency | Remarks |
| | | Clause | Reference | | | | |
| 5 | Materials | 5.1 to 5.2 | IS 12664(Part 1) | S | Each consignment | | No further testing is required if accompanied with the Test Certificate or ISI marked. |
| 7 | a) Shape and Design | 7.1 to 7.3 | IS 12664(Part 1) | R | Each SACH foot | | In case of any failure, those not conforming shall be rejected and shall not be marked |
| | b) Dimensional Requirements | 7.3, Table 1 | | R | Five | Each control unit | If any sample fails, Five more samples to be tested. Control unit to be accepted only if all Five samples pass. |
| | c) Adoption of Foot | 7.4 | | R | Five | Each control unit | If any sample fails, Five more samples to be tested. Control unit to be accepted only if all Five samples pass. |

Note-1: Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: The control unit and levels of control as decided by the Bureau are obligatory, to which the licensee shall comply with.