



**PRODUCT MANUAL FOR
ARTIFICIAL LIMBS – SACH FOOT FOR
LOWER EXTREMITY PROSTHESES – DESIGN AND DIMENSIONS
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.

1.	Product	:	IS 12644 (Part 1): 2003
	Title	:	Artificial Limbs – SACH For Lower Extremity Prostheses- 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		
	Size		

ANNEX A**Grouping Guidelines**

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

Type	Foot Sizes
SACH foot with internal heel laminated construction without toes	3, 5, 6, 7, 8, 9, 10, 11
SACH foot with internal heel moulded construction without toes	
SACH foot with internal heel moulded construction with toes	

2. The guidelines given below shall be followed for considering GoL/CSoL:
- i) One sample each of the smallest size and largest size from each Type shall be tested for all requirements to cover all sizes in that size range for the particular Type of SACH foot.
 - ii) However, if SACH foot with internal heel moulded construction with toes is tested, SACH foot with internal heel moulded construction without toes may also be covered.
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. 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)	---	---	---	Each consignment shall be accompanied with the Test Certificate.
6	Size and Dimensions	6, Table 1	IS 12664 (Part 1)	R	Five	Each control unit	If any sample fails, five more samples from the same control unit shall be tested. Control unit shall be accepted only if all five samples pass.
7	Shape and Design (except dimensional requirements)	7.1 to 7.3	IS 12664 (Part 1)	---	Each SACH foot	---	In case of any failure, those not conforming shall not be marked.
7.4	Adoption of Foot	7.4	IS 12664 (Part 1)	R	Five	Each control unit	If any sample fails, five more samples from the same control unit shall be tested. Control unit shall 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.

