उत्पाद मैन्यूअल
चिकित्सा सक्शन उपकरण भाग 1
विद्युत चालित सक्शन उपकरण
आईएस 18735 (भाग 1): 2023 के अनुसर

PRODUCT MANUAL FOR
Medical Suction Equipment Part 1
Electrically Powered Suction Equipment
as per IS 18735 (Part 1): 2023

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 18735 (Part 1): 2023
	शीर्षक **Title**	:	Medical Suction Equipment Part 1 Electrically Powered Suction Equipment
	संशोधनों की संख्या **No. of amendments**	:	None
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	As per Cl. 5 of IS 18735 (Part 1)
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	01 Suction Equipment with its accessories
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पेरामीटर** **Parameters to be Declared in Test Request**	:	As per Scope of Licence defined in Sl. No. 6 of PM below

3.	**परीक्षण उपकरणों की सूची List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण Possible tests in a day**	:	All possible test (as per IS 13450 (Part 1)) and Performance requirements as per Cl. 7
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 18735 (Part 1): 2023*** with the following scope:

Name of the product	Medical Suction Equipment Part 1 Electrically Powered Suction Equipment
Intended Use	For Hospital / For Home healthcare / For Field use and transport use
Internal Source	With / without battery powered

ANNEX -A

Grouping Guidelines

1. Medical Suction Equipment Part 1 Electrically Powered Suction Equipment is classified based on the following:

Intended Use	For Hospital / For Home healthcare / For Field use and transport use
Internal Source	With / without battery powered

2. For considering Grant of Licnce/ Change in Scope of Licence, sample from each type of intended use shall be tested.

3. However, the following relaxation may be considered:

    a) If Suction equipment having internal battery is tested, Suction equipment without internal battery may also be considered.

4. Firm shall declare the intended use of Suction equipment they intend to cover in the Licence. The Scope of Licence may be restricted based on the Manufacturing and Testing capabilities of the Manufacturer.

5. During the operation of the Licence, BO shall ensure that all the variety(ies) covered in the Scope of the Licence are tested in rotation, to the extent possible.

Note: Firm shall prepare and submit the Risk management file, Usability engineering file and Technical file covering the requirements specified in IS 18735 (Part 1): 2023.

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

Sl. No.	Tests used in with Clause Reference	Test Equipment
As per IS 13450 (Part 1) / IEC 60601 (part 1)		
1.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Ambient Temperature 5.3	Temperature & Air Velocity Meter
3.	Accessible Parts 5.9.2	Test Finger with accessibility test apparatus
4.	Humidity preconditioning treatment, 5.7	Conditioning chamber with temperature and humidity chamber
5.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
6.	Earth Leakage Current, 8.7.4.5, Touch Current, 8.7.4.6, Patient Leakage Current, 8.7.4.7	Figure 13 to Figure 18, Leakage Current Tester, metal foil
7.	Impedance and current carrying capability, 8.6.4	AC/DC voltage source, Multimeter/Earth Resistance Tester
8.	Dielectric Strength, 8.8.3	High Voltage Tester
9.	Creepage Distances And Air Clearances 8.9	Vernier Caliper, Filler Gauge
As per IS 18735		
10.	Collection containers (Cl. 6.2) Capacity (Cl. 6.2.1) Strength (Cl. 6.2.2)	 Air / vacuum pressure device Stopwatch / Timer
11.	Connections (Cl. 6.3) Suction tubing and intermediate tubing (Cl. 6.4)	Vernier Caliper Micrometer Scale Device for measuring ‘Degree of Collapse’
12.	Vacuum level indicators (Cl. 6.5)	Vacuum level indicators
13.	Environmental conditions for transport and storage (Cl. 6.6)	Conditioning Chamber with Temp., RH and Pressure controller
14.	Performance requirements (Cl. 7)	Stopwatch Beaker / Graduated cylinder Air / vacuum pressure device with airflow indicator Conditioning Chamber with Temp., RH and Pressure controller
15.	Additional/alternative requirements for suction equipment and suction tubing designed for field use or transport use (Cl. 8)	Stopwatch Beaker / Graduated cylinder Air / vacuum pressure device with airflow indicator Conditioning Chamber with Temp., RH and Pressure controller

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 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: *Electrically Powered Suction Equipment of same type 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. (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.

2.5.1 TECHNICAL FILE- Licencee shall maintain a Technical File for each model being manufactured by them. The Technical file shall be submitted to BIS at the time of Grant of Licence/ inclusion/ surveillance.

2.5.1.1 The Technical File shall be maintained till the End of Life of the model.

2.5.1.2 Licencee shall declare the frequency of periodic review of Technical file to BIS and record of review shall be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.5.1.3 For changes in the product which shall affect the Scope of the Licence, the modified product shall be treated as a different model and separate Technical File shall be maintained for the same.

2.5.1.4 The technical file shall consist of the following documents:

- A general description of the product;
- Product Manual and/ or Instructions for use;
- Instructions for repair/ service for the product/ components, if required;
- Frequency of periodic repair/ service for the product/ components, if required;
- Conceptual product design and manufacturing drawings and, where appropriate, list of components, electrical circuit design, etc with descriptions and explanations needed for the understanding of these drawings;
- A list of the all Indian/ International standards applied in full or in part during the conformity assessment process with copy of test certificate/ test report;
- Test reports/ Test Certificates and risk assessment file for the product and/ or components as per relevant Clauses of the Indian Standard;
- Copies of conformity assessment documentation for critical product components and accessories;

2.5.2 RISK MANAGEMENT FILE- The licencee shall maintain a Risk Management File for each model of Electrically Powered Suction Equipment as per the requirement of ISO 10079 (Part 4). The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

2.5.2.1 The Risk Management File shall be maintained till the End of Life of each model.

2.5.2.2 Licencee shall declare the frequency of periodic review of Risk Management File to BIS and record of review shall be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licencee shall inform the same to BIS and submit the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Risk Management File.

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

3.1 Marking on each Electrically Powered Suction Equipment meter shall be done as per Cl. 9.3 of ISO 10079 (Part 4).

3.2 **Additional Marking requirements**: The Electrically Powered Suction Equipment shall also be marked with the following additional requirement on its packaging:

a) "For BIS certification details please visit 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 R: required (or) S:Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
5	Materials	5	IS 18735 (Part 4)	S	One	Each consignment	No further testing is required if accompanied with the Test Certificate or ISI marked.
6.1	General requirements			S	One	Once in a month	
	General	6.1	IS 18735 (Part 4)	R	One	Each Control Unit	
	Collection containers	6.2	IS 18735 (Part 4)	R	One	Each Control Unit	
	Connections	6.3	IS 18735 (Part 4)	R	One	Each Control Unit	
	Suction tubing and intermediate tubing	6.4	IS 18735 (Part 4)	R	One	Each Control Unit	
	Vacuum level indicators	6.5	IS 18735 (Part 4)	R	One	Each Control Unit	
	Environmental conditions for transport and storage	6.6	IS 18735 (Part 4)	R	One	Each Control Unit	
6.2	Protection against ingress of solid objects and liquid	6.2	IS 18735 (Part 1)	S	One	Once in every six month	
6.3	Battery powered suction equipment	6.3	IS 18735 (Part 1)	R	One	Each Control Unit	
7	Performance requirements						
7.1	General	7	IS 18735 (Part 1)				
	Operating position	7.1	IS 18735 (Part 4)	R	One	Each Control Unit	
	Protection devices	7.2	IS 18735 (Part 4)	R	One	Each Control Unit	

	Noise	7.3	IS 18735 (Part 4)	R	One	Each Control Unit	
	Air leakage	7.4	IS 18735 (Part 4)	R	One	Each Control Unit	
	Vacuum levels and free air flows	7.5	IS 18735 (Part 4)	R	One	Each Control Unit	
	Accuracy	7.6	IS 18735 (Part 4)	R	One	Each Control Unit	
	Pharyngeal suction equipment	7.7	IS 18735 (Part 4)	R	One	Each Control Unit	
7.2	Effect of an interruption of power supply on the vacuum level and free air flow	7.2	IS 18735 (Part 1)	R	One	Each Control Unit	
8	Additional/alternative requirements for suction equipment and suction tubing designed for field use or transport use	8	IS 18735 (Part 4)	S	One	Once in every six month	
9	Information to be supplied by the manufacturer	9	IS 18735 (Part 4)	R	Each Suction Apparatus		