उत्पाद मैनुअल
एंडोस्कोप — चिकित्सा अन्तरीक्षण यन्त्र और अंतः चिकित्सा युक्तियाँ
भाग 1 सामान्य अपेक्षायें
आईएस 15732 (भाग 1): 2018/ आईएसओ 8600-1 : 2015 के अनुसार

PRODUCT MANUAL
Endoscopes — Medical Endoscopes and Endotherapy Devices
Part 1 General Requirements
According to IS 15732 (Part 1): 2018 / ISO 8600-1: 2015

यह उत्पाद नियमावली सभी क्षेत्रीय/शाखा कार्यालयों और लाइसेंसधारियों द्वारा विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना-I के अंतर्गत प्रमाणन के संचालन में एकरूपता और पारदर्शिता सुनिश्चित करने के लिए संदर्भ सामग्री के रूप में उपयोग की जाएगी। बीआईएस प्रमाणन प्राप्त करने के इच्छुक भावी आवेदक भी इस दस्तावेज़ का उपयोग कर सकते हैं।

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 15732 (Part 1): 2018 / ISO 8600-1: 2015
	शीर्षक / Title	:	Endoscopes — Medical Endoscopes and Endotherapy Devices Part 1 General Requirements
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूनाकरण दिशानिर्देश / Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	Components: As per Cl. 4.8 of IS 15732 (Part 1) *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**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	01 Equipment (with all the accessories)
d)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर / Parameters to be Declared in Test Request**		Same as the parameters given in scope of the licence under S. No. 6. *Note: Apart from the above, any other requirements/ parameters may also be declared as per the standard, as applicable.*

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3.	**परीक्षण उपकरण की सूची** **List of Test Equipment**	:	Please refer **ANNEX – B**
4.	**निरीक्षण एवं परीक्षण योजना** **Scheme of Inspection and Testing**	:	Please refer **ANNEX – C**
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	• Assessment of Risk Management File • Surface and edges, Cl 5.2 • Maximum insertion portion width, Cl 5.3 • Minimum instrument channel width, Cl 5.4 • Field of view, Cl 5.5 • Direction of view, Cl 5.6 Following clauses of IS 13450 (Part 2/Sec 18): 2014 (if applicable) • Power Supply, Cl. 201.4 • Power Input, Cl. 201. 4 • Accessible Parts, Cl. 201. 5 • Durability of markings, Cl. 201.7 • Protective Earth Terminal, Cl. 201.8 • Protective earthing of moving parts, Cl. 201.8 • Surface coatings, Cl. 201.8 • Plugs and Sockets, Cl. 201.8 • Earth Leakage Current, Cl.201.8 • Touch Current, Cl. 201.8 • Patient Leakage Current, Cl. 201.8 • Dielectric Strength, Cl. 201.8 *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 ready reference 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 15732 (Part 1): 2018/ ISO 8600-1: 2015** with the following scope:

Name of the product	Endoscopes — Medical Endoscopes and Endotherapy Devices Part 1 General Requirements
Model (s)	
Type	Rigid / Flexible
Size	From ….. upto and including ….. mm
Image pick up system	Lenses / Ultrasonic sensors
Image transmitting system	Optical (Lenses) / Optical (Fibre Bundles) / Electrical
Rating (for Electrical Endoscopic Equipments)	Rated Voltage …. V (or) Rated Voltage Ranges(s) ……V, Frequency…. Hz, Single phase / Three Phase, Rated Current …. A (or) Input power ….. W / VA

ANNEX - A
Grouping Guidelines

1. Endoscopes - Medical Endoscopes and Endotherapy Devices as per **IS 15732 (Part 1): 2018/ ISO 8600-1: 2015** are classified based on the following:

(i) Type	(a) Rigid (b) Flexible
(ii) Image pick up system	(a) Lenses (b) Ultrasonic sensors
(iii) Image transmitting system	(a) Optical (Lenses) (b) Optical (Fibre Bundles) (c) Electrical

2. Based on the above classification and grouping, following grouping guidelines shall be followed for considering Grant of Licence (GoL)/Change in Scope of Licence (CSoL):

   - Any one model of each type of Endoscopic Equipment shall be tested to cover the particular type.
   - Endoscopic equipment of lowest and highest size shall be tested to cover all sizes in the range.
   - If any one model of particular type of image pickup system is tested then all other models with the same image pickup system may be covered without further testing.
   - If any one model of particular type of image transmitting system is tested then all other models with the same image transmitting system may be covered without further testing.
   - For Electrical Endoscopic Equipments, any one model of a particular rating shall be tested to cover all other models with same rating.

3. Manufacturer shall submit scope declaration for each of the model of Endoscopes and Endotherapy devices they intend to cover in the scope of licence. The Scope of Licence may be restricted based on the Manufacturing and testing capabilities of the Manufacturer.

4. The manufacturer shall also declare the following for each model of Endoscopic Equipment intended to be covered in the scope of licence:
   (a) Field of view
   (b) Direction of view
   (c) Angle of deflection
   (d) Essential accessories (if any) supplied along with the model

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

ANNEX - B
List of Test Equipments
(Indicative List, For Guidance Only)

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Surface and edges, Cl 5.2 of IS 15732(Pt. 1): 2018	Visual Inspection
2.	Maximum insertion portion width & Minimum instrument channel width, Cl 5.3 & 5.4 of IS 15732(Pt. 1): 2018	Vernier Calliper Tape Measure or similar tool Steel scale Micrometer
3.	Field of view & Direction of view, Cl 5.5 & 5.6 of IS 15732(Pt. 1): 2018	Test setup as per IS 15732 (Part 3):2025 / ISO 8600-3:2019
4.	General requirement for Risk Management, Annex A of IS 15732: Pt. 1: 2018	• Inspection of the manufacturer's policy for determining criteria for RISK acceptability; • Inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and • Confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by the standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.
5.	Essential Performance, Cl. 201.4.3, IS 13450 Part 2: Sec 18, Cl. 4.3, IS 13450 Part 1	Inspection of Risk Management File
6.	Expected Service Life, Cl. 201.4, IS 13450 Part 2: Sec 18, Cl. 4.4, IS 13450 Part 1	Inspection of Risk Management File
7.	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS, Cl. 201.4, IS 13450 Part 2: Sec 18, Cl. 4.5, IS 13450 Part 1	Inspection of Risk Management File
8.	ME Equipment or ME System Parts that contact the patient, Cl. 201.4.6, IS 13450 Part 2: Sec 18	Inspection of Risk Management File
9.	Single Fault Condition for ME Equipment, Cl. 201.4.7, IS 13450 Part 2: Sec 18	Inspection of Risk Management File
10.	Components of ME Equipment, Cl. 4.8, IS 13450 Part 1	Compliance is checked by inspection and, where necessary, by test.
11.	Use of Component with High -Integrity Characteristics in ME Equipment, Cl. 201.4, IS 13450 Part 2: Sec 18, Cl. 4.9, IS 13450 Part 1	Inspection of Risk Management File
12.	Power Supply, Cl. 201.4, IS 13450 Part 2: Sec 18, Cl. 4.10, IS 13450 Part 1	Inspection of Accompanying document

13.	Power Input, Cl. 201. 4, IS 13450 Part 2: Sec 18, Cl. 4.11, IS 13450 Part 1	Power Input Test Apparatus/Power Analyzer/ Multimeter
14.	Ambient Temperature, Cl. 201. 5, IS 13450 Part 2: Sec 18, Cl. 5.3, IS 13450 Part 1	Temperature & Air Velocity Meter
15.	Applied Parts, Cl. 201.5, IS 13450 Part 2: Sec 18, Cl. 5.9.1, IS 13450 Part 1	Inspection of Accompanying document
16.	Accessible Parts, Cl. 201. 5, IS 13450 Part 2: Sec 18, Cl. 5.9.2, IS 13450 Part 1	Test Finger as per Figure 6 of IS 13450 Part 1, Test Hook as per Figure 7 of IS 13450 Part 1, Actuating Mechanisms
17	Humidity preconditioning treatment, Cl. 201.5, IS 13450 Part 2: Sec 18, Cl. 5.7, IS 13450 Part 1	Conditioning chamber with temperature and humidity chamber
18.	Durability of markings, Cl. 201.7, IS 13450 Part 2: Sec 18, Cl. 7.1.3, IS 13450 Part 1	Distilled water, ethanol 96%, Isopropyl alcohol, Stopwatch
19	Protective Earth Terminal, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.2, IS 13450 Part 1	Visual Inspection
20.	Protective earthing of moving parts, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.3, IS 13450 Part 1	Visual Inspection & Inspection of Risk Management File
21.	Impedance and current carrying capability, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.4, IS 13450 Part 1	AC/DC voltage source, Multimeter/ Earth Resistance Tester
22	Surface coatings, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.5, IS 13450 Part 1	Visual Inspection
23.	Plugs and Sockets, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.6, IS 13450 Part 1	Visual Inspection
24.	Potential Equalization Conductor, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.7, IS 13450 Part 1	Visual Inspection
25.	Functional Earth Terminal, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.6.8, IS 13450 Part 1	Visual Inspection
26.	Earth Leakage Current, Cl.201.8, IS 13450 Part 2: Sec 18, Cl.8.7.4.5, IS 13450 Part 1 Touch Current, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.7.4.6, IS 13450 Part 1 Patient Leakage Current, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.7.4.7, IS 13450 Part 1	Figure 13 to Figure 18 of IS 13450 Part 1, Leakage Current Tester, metal foil

27.	Dielectric Strength, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.8.3, IS 13450 Part 1	High Voltage Tester
28	Mechanical strength and resistance to heat of Insulation other than wire insulation, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.8.4.1, IS 13450 Part 1	Ball Test Apparatus as per Figure 21 of IS 13450 Part 1
29	Resistance to environmental stress of insulation other than wire, Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.8.4.2, IS 13450 Part 1	Inspection, by measurement and for natural latex rubber, Oxygen Cylinder
30	Creepage Distances and Air Clearances Cl. 201.8, IS 13450 Part 2: Sec 18, Cl. 8.9, IS 13450 Part 1	Vernier Caliper, Filler Gauge
31	HAZARDS associated with surfaces, corners and edges, Cl 201.9.3, IS 13450 Part 2, Sec 18	Inspection of Risk Management File
32	Protection against unwanted and excessive radiation HAZARDS, Cl. 201.10, IS 13450 Part 2: Sec 18	Inspection of Risk Management File
33	Protection against excessive temperatures and other hazards, Cl. 201.11, IS 13450 Part 2: Sec 18	Temp. Data logger
34	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME Equipment, Cl. 201.11.6, IS 13450 Part 2: Sec 18	Inspection of Risk Management File
35	Accuracy of controls and instruments and protection against hazardous outputs, Cl. 201.12, IS 13450 Part 2: Sec 18	Inspection of Risk Management File
36	Hazardous Situations and fault conditions, Cl. 201.13 IS 13450 Part 2: Sec 18	Inspection of Risk Management File
37	ME Systems, Cl. 201.16, IS 13450 Part 2: Sec 18, Cl. 16, IS 13450 Part 1	Visual inspection, inspection of appropriate documents or certificates and Risk Management File.
38	Electromagnetic compatibility, Cl. 201.17, IS 13450 Part 2: Sec 18	Inspection of the equipment and/or the Risk Management File, and Test as Specified in IEC 60601-1-2:2014 and IEC 60601-1- 2:2014/ AMD1:2020.

Note 1*: The above list is indicative only and may not be treated as exhaustive.*
Note 2*: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 15732(Pt. 1): 2018 for each model in the scope of licence.*
Note 3*: The Technical File and Risk Management File shall be maintained by the licensee till the End of Life for each model.*

ANNEX C
Scheme of Inspection and Testing

1. QUALITY ASSURANCE PLAN

1.1 It is expected that during operation of BIS licence manufacturers will implement a Quality Assurance Plan (QAP) 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 (QAP) defining the control unit (i.e. lot/batch etc.), the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and declare the arrangement for testing i.e. whether in-house or sub-contracting/ sharing for each applicable test and submit the same to BIS Branch Office for information. The manufacturer shall comply with the QAP and maintain test records in accordance with para 2.1.

1.3 Recommended Levels of Control/ Control Unit:

1.3.1 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1. Manufacturer has the discretion of declaring their own levels of control or accept the levels of control given in this document.

1.3.2 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.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING

The manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard for which they may have in-house test facilities. However, there is no obligation to maintain in-house laboratory. Licensee may use alternative arrangements for tests of the production as per the declared QAP. Various alternatives are available for operation of BIS certification as given below and the relevant guidelines for availing such relaxations by the manufacturers, as amended from time to time, are to be referred:

i) Shared testing resources like common facility,

ii) Cluster based testing facility,

iii) Sub-contracting to outside laboratories which may either be:

a) BIS recognised/ empanelled laboratories, or

b) Any accredited laboratory as per ISO/IEC 17025

2.1 Test Records- The manufacturers shall maintain test records for the tests carried out (either in-house or at a sub-contracted or at shared test facility) to establish conformity of the product to the Standard for operation of licence. For the tests being subcontracted or conducted at a shared test facility, test results issued by the laboratories or test facilities, shall be made available for inspection by BIS.

2.1.1 **Technical File**- Licensee 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.

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

2.1.1.2 Licensee shall declare the frequency for periodic review in Technical file to BIS and record of review to be maintained. In case of any change in the Technical file due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Technical File to BIS within 30 days of issue of the revised/ modified Technical File.

2.1.1.3 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.

2.1.1.4 The technical file shall consist of the following documents:

2.1.1.4.1 A general description of the product;

2.1.1.4.2 Product Manual and/ or Instructions for use;

2.1.1.4.3 Instructions for repair/ service for the product/ components, if required;

2.1.1.4.4 Frequency of periodic repair/ service for the product/ components, if required;

2.1.1.4.5 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;

2.1.1.4.6 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;

2.1.1.4.7 Test reports/ Test Certificates and Risk Assessment File for the product and/ or components as per relevant Clauses of the Indian Standard;

2.1.1.4.8 Copies of Conformity Assessment documentation for critical product components;

2.1.1.4.9 Copy of BIS licences for the product/ components, wherever applicable;

2.1.1.4.10 A copy of the Declaration of Conformity for other International Standards;

2.1.1.4.11 Other documents, if found necessary by the manufacturer and/ or by BIS may also be a part of the Technical File

2.1.2 **Risk Management File**- The licensee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS 15732 (Part 1): 2018/ ISO 8600-1: 2015. The Risk Management File shall be submitted to BIS at the time of Grant of Licence/Inclusion/Surveillance.

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

2.1.2.2 Licensee shall declare the frequency for periodic review of Risk Management File and record of review in the file to be maintained. In case of any change in the Risk Management File due to any periodic review/ change in the product, the licensee shall inform the same to BIS at the earliest and provide the copy of the latest version of Risk Management File to BIS within 30 days of issue of the revised/ modified Technical File.

3. PACKING AND MARKING

The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Endoscopic Equipment provided always that the Endoscopic Equipment so marked conforms to each requirement of the specification.

3.1 Marking and Packaging of Endoscopic Equipment shall be done as per Cl. 6 & Cl. 8 of IS 15732 (Part 1): 2018 / ISO 8600-1: 2015.

3.2 **Additional Marking requirements**: The Endoscopic Equipment shall also be marked with the following additional requirement on the product and its packaging:

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

4. REJECTION

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

(Recommended Levels of Control by BIS- for Guidance Only)

(1)				(2)		
Test Details				**Levels of Control**		
Cl.	**Requirement**	**Test Method**		**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**			
5.2	Surface and edges	5.2	IS 15732 (Part 1)	One	Each Medical Equipment	
5.3	Maximum insertion portion width	5.3	IS 15732 (Part 1)	One		
5.4	Minimum instrument channel width	5.4	IS 15732 (Part 1)	One		
5.5	Field of view	5.5	IS 15732 (Part 1)	One	Each Medical Equipment	
5.6	Direction of view	5.6	IS 15732 (Part 1)	One		
4.10	Deflection control system for the controllable portion	4.10	IS 15732 (Part 1)	One		
4.8	Biological compatibility	4.8	IS 15732 (Part 1)	One	Once in three years	Refer Note 1
4.7	Safety	4.7	IS 15732 (Part 1)	As given below		
201.4	**General requirements**					
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1 201.4.1	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Each Medical Equipment	
4.2	Risk management process for ME equipment or ME systems	4.2	IS 13450 (Part 1)	One		
4.3	Essential Performance	4.3 201.4.3. 101	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.4	EXPECTED SERVICE LIFE	4.4 201.4.4	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	One		
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6 201.4.6	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	4.7 201.4.7	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
4.8	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	One	Each Consignment	No further testing if accompanied with Test Certificate or ISI Mark or covered in Risk Management file
4.9	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	4.9	IS 13450 (Part 1)	One		
4.10	Power supply	4.10.1 4.10.2	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.11	Power input	4.11	IS 13450 (Part 1)	One		

201.7	**ME Equipment identification, marking and documents**					
7.1	General	7	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts	7.2 201.7.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	One		
7.4	Marking of controls and instruments	7.4 201.7.4.3	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
7.5	Safety signs	7.5	IS 13450 (Part 1)	One		
7.6	Symbols	7.6 201.7.6.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
7.7	Colours of the insulation of conductors	7.7	IS 13450 (Part 1)	One		
7.8	Indicator lights and controls	7.8	IS 13450 (Part 1)	One		
7.9	ACCOMPANYING DOCUMENTS	7.9 201.7.9.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
201.8	**Protection against electrical hazards from ME Equipment**					
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.3	Classification of APPLIED PARTS	8.3 201.8.3	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
8.4	***Limitations of voltage, current or energy***					
8.4.2(a)	The currents from, to or between Patient connections	8.7.4	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.4.2(b)	The Leakage Currents from, to or between Accessible parts	8.7.4	IS 13450 (Part 1)	One		
8.4.2(c)	Other accessible parts	8.4.2	IS 13450 (Part 1)	One	Once in three years	Refer Note 1
8.4.2(d)	Internal parts that are accessible	8.4.2	IS 13450 (Part 1)	One		
8.4.3	ME equipment intended to be connected to a power source by a plug	8.4.3	IS 13450 (Part 1)	One		
8.4.4	Internal capacitive circuits	8.4.4	IS 13450 (Part 1)	One		
8.5	***Separation of Parts***					
8.5.1.2	Means of Patient Protection (MOPP)	8.5.1.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Once in three years	Refer Note 1
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	8.5.1.2		One		
8.5.2	Separation of PATIENT CONNECTIONS	8.5.2 201.8.5.2		One		
8.5.3	MAXIMUM MAINS VOLTAGE	8.5.3		One		

8.5.4	WORKING VOLTAGE	8.5.4	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Once in three years	Refer Note 1
8.5.5	DEFIBRILLATION - PROOF APPLIED PARTS	8.5.5		One		
8.5.5.1	Defibrillation Protection	8.5.5.1		One		
8.5.5.2	Energy Reduction Test	8.5.5.2		One		
8.6	***Protective earthing, functional earthing and potential equalization of ME EQUIPMENT***					
8.6.1	Applicability of requirements	8.6.1	IS 13450 (Part 1)	One	Once in three years	Refer Note 1
8.6.2	PROTECTIVE EARTH TERMINAL	8.6.2		One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.6.3	Protective earthing of moving parts	8.6.3		One		
8.6.4	Impedance and current-carrying capability	8.6.4		One	Once in three years	Refer Note 1
8.6.5	Surface Coatings	8.6.5		One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.6.6	Plugs and sockets	8.6.6		One		
8.6.7	POTENTIAL EQUALIZATION CONDUCTOR	8.6.7		One		
				One		
8.6.8	FUNCTIONAL EARTH TERMINAL	8.6.8		One		
8.6.9	CLASS II ME EQUIPMENT	8.6.9		One		
8.7	***Leakage Currents and Patient Auxiliary Currents***					
8.7.1	General Requirements	8.7.1	IS 13450 (Part 1)	One	Once in three years	Refer Note 1
8.7.2	SINGLE FAULT CONDITIONS	8.7.2				
8.7.3	Allowable values	8.7.3				
8.7.4	Measurements	8.7.4				
8.8	***Insulation***					
8.8.2	Distance through solid insulation or use of thin sheet material	8.8.2	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.8.3	Dielectric strength	8.8.3 201.8.8.3	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
8.8.4.1	Mechanical strength and resistance to heat	8.8.4.1	IS 13450 (Part 1)	One	Once in three years	Refer Note 1
8.8.4.2	Resistance to environmental stress	8.8.4.2	IS 13450 (Part 1)	One		
8.9	***Creepage Distances and Air Clearances***					
8.9.1	Values	8.9.1 201.8.9.1	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Once in three years	Refer Note 1
8.9.2	Applications	8.9.2	IS 13450 (Part 1)	One		
8.9.3	Spaces filled by insulating compound	8.9.3	IS 13450 (Part 1)	One		
8.9.4	Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES	8.9.4	IS 13450 (Part 1)	One		

8.10	***Components and wiring***					
8.10.1	Fixing of components	8.10.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.10.2	Fixing of wiring	8.10.2	IS 13450 (Part 1)	One		
8.10.3	Connections between different parts of ME EQUIPMENT	8.10.3	IS 13450 (Part 1)	One		
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices	8.10.4	IS 13450 (Part 1)	One		
8.10.5	Mechanical protection of wiring	8.10.5	IS 13450 (Part 1)	One		
8.10.6	Guiding rollers for insulated conductors	8.10.6	IS 13450 (Part 1)	One		
8.10.7	Insulation of internal wiring	8.10.7	IS 13450 (Part 1)	One		
8.11	***MAINS PARTS, components and layout***					
8.11.1	Isolation from Supply mains	8.11.1	IS 13450 (Part 1)	One	Once in three years	Refer Note 1,3
8.11.2	Multiple Socket Outlets	8.11.2 8201.8.1 1.2	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		Refer note 1
8.11.3	*Power Supply Cords*					
8.11.3.1	Application	8.11.3.1	IS 13450 (Part 1)	One	Each Medical Equipment	Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.11.3.2	Types	8.11.3.2	IS 13450 (Part 1)	One		
8.11.3.3	Cross-sectional area of POWER SUPPLY CORD conductors	8.11.3.3	IS 13450 (Part 1)	One		
8.11.3.4	Appliance Couplers	8.11.3.4	IS 13450 (Part 1)	One		
8.11.3.5	Cord anchorage	8.11.3.5	IS 13450 (Part 1)			
8.11.3.6	Cord guards	8.11.3.6	IS 13450 (Part 1)			
8.11.4	Mains terminal devices	8.11.4	IS 13450 (Part 1)	One		
8.11.5	Mains fuses and over current releases	8.11.5	IS 13450 (Part 1)	One		
8.11.6	Internal wiring of the Mains Part	8.11.6	IS 13450 (Part 1)	One		
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**					
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3 201.9.3	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Once in three years	Refer note 1
201.9.4	Instability HAZARDS	201.9.4.2	IS 13450 (Part 2/ Sec 18)	One		
9.6	Audible acoustic energy	9.6 201.9.6.2 .1.101	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7.1 to 9.7.4 201.9.7.6 201.9.7.7	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		

201.10	**Protection against unwanted and excessive radiation HAZARDS**					
10.1	X-Radiation	10.1	IS 13450 (Part 1)	One	Once in three years	Refer note 1
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	One		
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	One		
10.4	Lasers	10.4 201.10.4	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
201.10.5	Other visible electromagnetic radiation	201.10.5	IS 13450 (Part 2/ Sec 18)	One		
201.10.6	Infrared radiation	201.10.6	IS 13450 (Part 2/ Sec 18)	One		
201.10.7	Ultraviolet radiation	201.10.7	IS 13450 (Part 2/ Sec 18)	One		
201.11	**Protection against excessive temperatures and other HAZARDS**					
11.1	Excessive temperatures in ME EQUIPMENT	11.1 201.11.1	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Once in three years	Refer note 1
11.2	Fire Prevention	11.2	IS 13450 (Part 1)			
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)			
11.4	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable anaesthetics	11.4	IS 13450 (Part 1)			
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)			
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6, 201.11.6 .5	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Each Medical Equipment	
11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7 201.11.7	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One	Once in three years	Refer note 1
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8 201.11.8 .101	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)			
201.11 .101	INTERCONNECTION CONDITIONS	201.11.1 01	IS 13450 (Part 2/ Sec 18)			
201.12	**Accuracy of controls and instruments and protection against hazardous outputs**					
12.1	Accuracy of controls and instruments	12.1	IS 13450 (Part 1)	One	Each Medical Equipment	
12.2	USABILITY of ME EQUIPMENT	12.2 201.12.2	IS 13450 (Part 1) IS 13450 (Part 2/Sec 18)	One		
12.3	ALARM SYSTEMS	12.3 201.12.3	IS 13450 (Part 1) IS 13450 (Part 2/Sec 18)	One		

12.4	Protection against hazardous output conditions	12.4 201.12.4 .4	IS 13450 (Part 1) IS 13450 (Part 2/Sec 18)	One	Once in three years	Refer note 1
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**					
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13 201.13.1. 101	IS 13450 (Part 1) IS 13450 (Part 2/Sec 18)	One	Once in three years	Refer note 1
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**					
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	14	IS 13450 (Part 1)	One	Once in three years	Refer note 1
201.15	**Construction of ME EQUIPMENT**					
15.1	Arrangements of controls and indicators of ME EQUIPMENT	15.1	IS 13450 (Part 1)	One	Once in three years	Refer note 1
15.2	Serviceability	15.2	IS 13450 (Part 1)	One		
15.4	ME EQUIPMENT components and general assembly	15.4 201.15.4 .1	IS 13450 (Part 1) IS 13450 (Part 2/ Sec 18)	One		
15.5	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	15.5	IS 13450 (Part 1)	One	Once in three years	
201.16	**ME SYSTEMS**					
16.1	General requirements for the ME SYSTEMS	16.1	IS 13450 (Part 1)	One	Once in three years	Refer note 1
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM	16.2	IS 13450 (Part 1)	One		
16.3	Power Supply	16.3	IS 13450 (Part 1)	One		
16.4	Enclosures	16.4	IS 13450 (Part 1)	One		
16.5	Separation Devices	16.5	IS 13450 (Part 1)	One		
16.6	Leakage Current	16.6	IS 13450 (Part 1)	One		
201.17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**					
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	17	IS 13450 (Part 1)	One	Once in three years	Refer note 1
202	**Electromagnetic disturbances – Requirements and tests**					
202	Electromagnetic disturbances – Requirements and tests	202 202.6.2. 1.10	IS 13450 (Part 1/ Sec 2) IS 13450 (Part 2/Sec 12)	One	Once in three years	Refer note 1

Note-1: *In addition, the test(s) shall be done whenever there is a change in design of the product, components or parts.*

Note-2: *Report of the Factory Sample drawn for complete testing by BIS will be shared with the manufacturer. During the operation of licence, licensee has to ensure that all the model(s) covered in the scope of the licence are tested in rotation.*