चिकित्सा विद्युत उपकरण
भाग 2 बुनियादी सुरक्षा और आवश्यक प्रदर्शन निष्पादन के लिए विशेष आवश्यकताएँ
धारा 24 इंफ्युजन पम्प और नियंत्रक
आई एस 13450 (भाग 2 / अनुभाग 24): 2019

PRODUCT MANUAL FOR
Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Sec 24 Infusion pumps and controllers IS 13450 (Part 2 / Sec 24): 2019

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 13450 (Part 2 / Sec 24): 2019 / IEC 60601-2-24: 2012
	शीर्षक **Title**	:	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Sec 24 Infusion pumps and controllers
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	Components – As per Cl 4.8 of IS 13450 (Part 1):2018
b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Please refer **ANNEX – A**
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 machine (with all the accessories)
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**	:	Please refer **ANNEX – D**
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 13450 (Part 2 / Sec 24): 2019 / IEC 60601-2-24: 2012*** with the following scope:

Name of the product	Medical Electrical Equipment Part 2 Particular Requirements for Basic Safety and Essential Performance Sec 24 Infusion pumps and controllers
Model	
Type of Pump	Syringe (or) Container Infusion Pump / Volumetric Infusion pump
Type of flow	Continuous / non-continuous / discrete delivery of a bolus / PROFILE PUMP
	With intended bolus / unintended bolus
Maximum Infusion Pressure	(To be declared by the manufacturer)
Rating	Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac Frequency …. Hz, Single phase / Three Phase, Rated Current …. A, Input power …….W (or) ….kVA
Internal Power Source	With / without internal power source
Type	Stationary (or) Fixed / Mobile / Portable
Protection against electric shock	Class – I / Class – II Type BF Applied Parts / Type CF Applied Parts
Protection against harmful ingress of water or particulate matter	
Suitability for use in oxygen rich environment	Suitable/ Not suitable
Accessories to be supplied with the Infusion pumps and controllers	

ANNEX -A
Grouping Guidelines

1. Manufacturer shall submit the declaration for each of the parameters as specified in scope of the licence (as per Sl. No. 6 above) of each model of 'Infusion pumps and controllers' they intend to cover in the scope of licence.

2. For Grant of Licnce/ Change in Scope of Licence, each 'Model' of 'Infusion pumps and controllers' is to be tested. However, change in aesthetic (i.e. colour, visual design, etc) may not be treated as different model.

3. 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.

Note: Firm shall declare the following parameters for each of the Model of Infusion pumps and controllers:

a) Any associated equipment to be used with Infusion pumps and controllers

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

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Power Input, 4.11	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Leakage currents and patient auxiliary currents, 8.7	Multimeter / Electrical Safety Analyzer
3.	Dielectric Strength, 8.8.3	High Voltage Tester
4.	Interruption of power supply/supply mains, 11.8	
5.	Protection against excessive temperatures and other hazards, 201.11	Temp. Data logger
6.	Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRING OR CONTAINER PUMPS, 201.12.1.102	Weighing Balance Infusion Pump Analyser
7.	Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1, 201.12.1.103	
8.	Accuracy tests for INFUSION PUMP FOR AMBULATORY USE type 2, 201.12.1.104	
9.	Accuracy tests for INFUSION PUMP type 3, 201.12.1.105	
10.	Accuracy tests for INFUSION PUMP type 4, 201.12.1.106	
11.	Accuracy tests for INFUSION PUMP type 5, 201.12.1.107	
12.	Protection against overinfusion, 201.12.4.4.101	
13.	Protection against overinfusion FREE FLOW conditions, 201.12.4.4.102	
14.	MAXIMUM INFUSION PRESSURE, 201.12.4.4.103	
15.	Protection against UNINTENDED BOLUS volumes and by occlusion, 201.12.4.4.104	Test apparatus as per Fig. 201.112, thermometer, & RH indicator, Infusion Pump Analyser

Note 1: The licensee shall maintain a Technical file and Risk Management File as per the provisions of IS 13450 (Part 2 / Sec 24): 2019 for each model in the scope of license.

Note 2: 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 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 in preparing the Quality Assurance Plan, recommended levels of control are given in Table 1.

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. 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 Infusion pumps and controllers as per the requirement of IS 13450 (Part 2 / Sec 24): 2019. 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 Infusion pumps and controllers provided always that the Infusion pumps and controllers so marked conforms to each requirement of the specification.

3.1 Marking shall be done as per Cl. 201.7 of IS 13450 (Part 2 / Sec 24): 2019.

3.2 **Additional Marking requirements**: The Infusion pumps and controllers shall also be marked with the following additional requirement on each product and 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 Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
201.4	**General requirements**						
4.1	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	Each Medical Equipment		Technical documentation - Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.
4.2	Risk management process for ME equipment or ME systems	4.2.1 4.2.2 4.2.3 201.4.2.3.101	IS 13450 (Part 1) IS 13450-2-24	R			
4.3	Essential Performance	4.3	IS 13450 (Part 1)	R			
4.4	EXPECTED SERVICE LIFE	4.4	IS 13450 (Part 1)	R	Each Medical Equipment		Technical documentation - Compliance shall be checked by inspection of the RISK MANAGEMENT FILE.
4.5	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	R			
4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT	4.6	IS 13450 (Part 1)	R			

4.7	SINGLE FAULT CONDITION for ME EQUIPMENT	13.1 13.2	IS 13450 (Part 1) IS 13450-2-24	S	One	Once in a month for each type of model manufactured during that period	
4.8	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	R	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)				
4.10	**Power supply**						
4.10.1	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2	IS 13450 (Part 1)	R			
4.11	Power input	4.11	IS 13450 (Part 1)	R			
201.7	**ME Equipment identification, marking and documents**						
7	ME Equipment Identification, marking and documents	7	IS 13450 (Part 1)	R	Each Medical Equipment		
201.7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts ACCESSORIES	201.7.2 201.7.2.1 201.7.2.4	IS 13450 (Part 1) IS 13450-2-24	R			
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts	7.3	IS 13450 (Part 1)	R			

7.4	Marking of controls and instruments	7.4	IS 13450 (Part 1)	R			
7.5	Safety signs	7.5		R			
7.6	Symbols	7.6		R	Each Medical Equipment		
7.7	Colours of the insulation of conductors	7.7	IS 13450 (Part 1)	R			
7.8	Indicator lights and controls	7.8	IS 13450 (Part 1)	R			
7.9	ACCOMPANYING DOCUMENTS	7.9 201.7.9.2.101	IS 13450 (Part 1) IS 13450-2-24	R			
201.7.9.3	Technical description	201.7.9.3.1 201.7.9.3.101	IS 13450 (Part 1) IS 13450-2-24	R			
201.8	**Protection against electrical hazards from ME Equipment**						
8.1	Fundamental rule of protection against electric shock	8.1	IS 13450 (Part 1)	R	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
8.2	Requirements related to power sources	8.2	IS 13450 (Part 1)	R			
8.3	Classification of APPLIED PARTS	8.3 201.8.3.101	IS 13450 (Part 1) IS 13450-2-24	R			
8.4	Limitations of voltage, current or energy	8.4	IS 13450 (Part 1)	R	One	Once in a month for each type of model manufactured during that period	
8.5	Separation of Parts	8.5	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
8.6							

8.6	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	8.6	IS 13450 (Part 1)	R	One	Once in a month for each type of model manufactured during that period
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS	8.7	IS 13450 (Part 1)	R		
8.8	Insulation	8.8	IS 13450 (Part 1)	S		
8.9	CREEPAGE DISTANCES and AIR CLEARANCES	8.9	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
8.10	Components and wiring	8.10	IS 13450 (Part 1)	S	One	
8.11	MAINS PARTS, components and layout	8.11	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
201.9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**					
9.1	MECHANICAL HAZARDS of ME EQUIPMENT	9.1	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
9.2	MECHANICAL HAZARDS associated with moving parts	9.2	IS 13450 (Part 1)	S	One	
9.3	MECHANICAL HAZARD associated with surfaces, corners and edges	9.3	IS 13450 (Part 1)	S	One	
9.4	Instability HAZARDS	9.4,	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period
9.5	Expelled parts HAZARD	9.5	IS 13450 (Part 1)	S	One	

9.6	Audible acoustic energy	9.6	IS 13450 (Part 1)	S	One	
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure	9.7	IS 13450 (Part 1)	S	One	
9.8	MECHANICAL HAZARDS associated with support systems	9.8	IS 13450 (Part 1)	S	One	
201.10	**Protection against unwanted and excessive radiation HAZARDS**					
10.1	X-Radiation	10.1	IS 13450 (Part 1)	S	One	Once in every three years for each type of model manufactured during that period
10.2	Alpha, beta, gamma, neutron and other particle radiation	10.2	IS 13450 (Part 1)	S	One	
10.3	Microwave radiation	10.3	IS 13450 (Part 1)	S	One	
10.4	Lasers	10.4	IS 13450 (Part 1)	S	One	
10.5	Other visible electromagnetic radiation	10.5	IS 13450 (Part 1)	S	One	
10.6	Infrared radiation	10.6	IS 13450 (Part 1)	S	One	
10.7	Ultraviolet radiation	10.7	IS 13450 (Part 1)	S	One	
201.11	**Protection against excessive temperatures and other HAZARDS**					
11.1	Excessive temperatures in ME EQUIPMENT	11.1	IS 13450 (Part 1)	S	One	Once in a moth for each type of model manufactured during that period

11.2	Fire Prevention	11.2	IS 13450 (Part 1)	S	One	
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.3	IS 13450 (Part 1)	S	One	
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics	11.4	IS 13450 (Part 1)	S	One	
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents	11.5	IS 13450 (Part 1)	S	One	
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	IS 13450 (Part 1)	R	One	
201.11.6.3	Spillage on ME EQUIPMENT and ME SYSTEMS	201.11.6.3	IS 13450-2-24	R	One	
201.11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS	201.11.6.5	IS 13450-2-24	R	One	

11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS	11.7	IS 13450 (Part 1)	R	One	Once in 03 years	
11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8	IS 13450 (Part 1)	R	Every Medical Equipment		
201.11.8	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	201.11.8	IS 13450-2-24	R	Every Medical Equipment		
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)	R	Each Medical Equipment		
201.12.1.101	*General formula	201.12.1.101	IS 13450-2-24	R			
201.12.1.102	Accuracy tests for VOLUMETRIC INFUSION CONTROLLERS, VOLUMETRIC INFUSION PUMPS and SYRINGE OR CONTAINER PUMPS	201.12.1.102	IS 13450-2-24	R			
201.12.1.103	Accuracy tests for INFUSION PUMPS FOR AMBULATORY USE type 1	201.12.1.103	IS 13450-2-24	R			
201.12.1.104	Accuracy tests for INFUSION PUMP FOR AMBULATORY USE type 2	201.12.1.104	IS 13450-2-24	R			
201.12.1.105	Accuracy tests for INFUSION PUMP type	201.12.1.105	IS 13450-2-24	R			

	3					
201.12.1.106	Accuracy tests for INFUSION PUMP type 4	201.12.1.106	IS 13450-2-24	R		
201.12.1.107	Accuracy tests for INFUSION PUMP type 5	201.12.1.107	IS 13450-2-24	R		
12.2	USABILITY of ME EQUIPMENT	12.2	IS 13450 (Part 1)	R		
12.3	ALARM SYSTEMS	12.3	IS 13450 (Part 1)	R		
12.4	Protection against hazardous output	12.4.1 to 12.4.4	IS 13450 (Part 1)	R	Each Medical Equipment	
201.12.4.1	Intentional exceeding of safety limits	201.12.4.1	IS 13450-2-24	R		
201.12.4.4.101	Protection against overinfusion	201.12.4.4.101	IS 13450-2-2	R		
201.12.4.4.102	Protection against overinfusion FREE FLOW conditions	201.12.4.4.102				
201.12.4.4.103	MAXIMUM INFUSION PRESSURE	201.12.4.4.103				
201.12.4.4.104	Protection against UNINTENDED BOLUS volumes and by occlusion	201.12.4.4.104				
201.12.4.4.105	Reverse delivery	201.12.4.4.105				

201.12.4.4.106	ME EQUIPMENT and drop sensor orientation	201.12.4.4.106					
201.12.4.4.107	Protection against air infusion	201.12.4.4.107					
201.12.4.4.108	ADMINISTRATION SETS – Operational characteristics	201.12.4.4.108					
201.12.4.4.109	Protection against underinfusion	201.12.4.4.109					
201.13	**HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**						
13	HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	13	IS 13450 (Part 1)	S	One	Once in a month for each type of model manufactured during that period	
201.13.2.6	Leakage of liquid	201.13.2.6	IS 13450-2-24	S	One		
201.14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**						
14	Programmable Electrical Medical Systems (PEMS)	14	IS 13450 (Part 1)	S	One	Once in 03 years	For each type of model manufactured during the period
201.15	**Construction of ME EQUIPMENT**						
15.1	Arrangements of controls and indicators of ME EQUIPMENT	15.1	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	
15.2	Serviceability	15.2	IS 13450 (Part 1)	S			
15.3	Mechanical strength	15.3	IS 13450 (Part 1)	S	One	Once in every six month for each type of model manufactured during that period	

15.4 201.15.4.4	Indicators	15.4 201.15.4.4	IS 13450 (Part 1) IS 13450-2-24	S	One	Once in every six month for each type of model manufactured during that period	
201.15.101	Fitting of the syringe/container	201.15.101	IS 13450-2-24	S	One	One	Once in a month for each type of model manufactured during that period
201.15.102	Fitting of the ADMINISTRATION SET	201.15.102	IS 13450-2-24	S	One		
201.15.103	*Use errors	201.15.103	IS 13450-2-24	S	One		
201.16	**ME SYSTEMS**						
16	ME SYSTEMS	16	IS 13450 (Part 1)	S	Each Medical Equipment		Testing and assessment of the product to be done as specified in the Technical File and Risk Assessment File
201.17	**Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**						
17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	17	IS 13450 (Part 1)	S	One	Once in 03 years	For each type of manufactured during the period
202	**Electromagnetic disturbances – Requirements and tests**						
202	Electromagnetic disturbances – Requirements and tests	202 202.6.2.1.3 202.6.2.2.1	IS 13450-1-2 IS 13450-2-24 IS 13450-2-24	S	One	Once in 03 years	For each type of model manufactured during the period
206	Usability	206	IS 13450-1-6	S	One	Once in a year	For each type of model manufactured during the period
208	General requirements, tests and guidance for alarm systems in	208	IS 13450-1-8	S	One	Once in 03 years	For each type of model manufactured during the period

	medical electrical equipment and medical electrical systems						
208.6.1.2.101	ALARM CONDITION priorities and related situations	208.6.1.2.101	IS 13450-2-24	R	One	Each Medical Equipment	
208.6.3.3.1	Characteristics of auditory ALARM SIGNALS	208.6.3.3.1	IS 13450-2-24	S	One	Once in a year	For each type of model manufactured during the period
208.6.3.3.2	Volume of auditory ALARM SIGNALS and INFORMATION SIGNALS	208.6.3.3.2	IS 13450-2-24	S	One	Once in a year	For each type of model manufactured during the period
208.6.3.3.2.101	Volume of auditory ALARM SIGNALS	208.6.3.3.2.101	IS 13450-2-24	S	One	Once in a year	For each type of model manufactured during the period
208.6.3.3.2.102	AUDIO PAUSED period	208.6.3.3.2.102	IS 13450-2-24	S	One	Once in a year	For each type of model manufactured during the period