



**PRODUCT MANUAL FOR
MEDICAL ELECTRICAL EQUIPMENT- DIAGNOSTIC X-RAY MACHINE
PART 1- MECHANICAL & ELECTRICAL SAFETY
ACCORDING TO IS 7620 (Part 1): 1986**

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, 2019 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate.

1.	Product	:	IS 7620 (Part 1): 1986
	Title	:	Medical Electrical Equipment- Diagnostic X-ray Machine - Mechanical & Electrical Safety
	No. of Amendments	:	3
2.	Sampling Guidelines:		
a)	Raw material	:	As per Cl 3.1.2 of IS 7620 (Part 1)
b)	Grouping guidelines	:	Each variety to be tested for GoL/ CSoL
c)	Sample Size	:	One
3.	List of Test Equipment	:	Please refer ANNEX – A .
4.	Scheme of Inspection and Testing	:	Please refer ANNEX – B .
5.	Possible tests in a day	:	As the licence is operated on Factory Testing basis, complete testing of a sample shall be done in factory.
6.	Scope of the Licence :		
	Licence is granted to use Standard Mark as per IS 7620 (Part 1): 1986 with the following scope: “Stationary/ Mobile Medical electrical equipment- Diagnostic X-ray machine _____ type, _____ frequency generator, for rated line voltage _____ V, frequency _____ Hz, _____ phase, current _____ A, Rated Peak Output Voltage _____ kVp, output power _____ W” <i>Other relevant aspects may also be mentioned in the scope.</i>		

ANNEX A**List Of Test Equipment***Major test equipment required to test as per the Indian Standard*

Sr. No.	Test Equipment	Tests used in with Clause Reference
1	Vernier Callipers	Sheet metal thickness- Cl 3.1.4
		Metal plate thickness- Cl 3.6.11
		Clearances – Cl 3.8.7
		Barrier thickness- Cl 3.8.8
2	Scale	X-Ray table drift- Cl 3.11.1
3	Steel probe	Enclosure protection test- Cl 3.1.9
4	a)Humidity chamber b)Megger	Insulation resistance test – Cl 6.2.1 & Cl 6.2.2
5	HV tester	High Voltage test- Cl 6.3
6	Leakage current tester	Leakage current test- Cl 6.4
7	Earth Resistance tester with a)Ammeter b)Voltmeter c) Current Source	Earth Resistance test- Cl 6.2.5
8	a) Dummy Load b) Multimeter	Testing of Over current protective devices and meters- Cl 6.6
9	Temperature indicator with thermocouples	Temperature rise test – Cl 3.4, Cl 6.7

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

ANNEX B

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 equipment.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. LABELLING AND MARKING – As per the requirements of IS 7620 (Part 1): 1986.

4. CONTROL UNIT – All X-ray machine, tables, tubes stands of the same type, design and rating manufactured in a month shall constitute a 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.

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 Methods			No. of Sample	Frequency	
		Clause	Ref				
3	General requirements	3, 6.1	IS 7620 (Part 1)	-	Each machine*		
4	Marking	4		-	Each machine		
6.2	Insulation resistance	6.2.1		R	Each machine		
		6.2.2		R	One	Once in six months of the same type, design and rating	
6.3	High Voltage test	6.3		R	Each machine		
6.4	Leakage current	6.4		R			
6.5	Earth resistance test	6.5		R			
6.6	Testing of over-current protective device for X-Ray control	6.6.1, 6.6.2		R	One	Once in six months of the same type, design and rating	
6.7	Temperature rise test	3.4, 6.7		R			

* The components and parts of X-Ray equipment under mandatory certification shall be ISI marked. Other components/ parts shall be either ISI marked or a test certificate shall be obtained from the supplier of components or parts.

Note: Levels of control given in column 3 are obligatory in nature, to which the licensee shall comply with.