



**PRODUCT MANUAL FOR
IN-VITRO DIAGNOSTIC (IVD) DEVICE — AUTOMATED CLINICAL CHEMISTRY ANALYZER
PART 1 WET CHEMISTRY ANALYZER
ACCORDING TO IS 17717 (PART 1): 2023**

**उत्पाद मैनुअल
इन-विट्रो डायग्नोस्टिक (आईवीडी) डिवाइस - स्वचालित क्लिनिकल रसायन विश्लेषक
भाग 1 गीला रसायन विश्लेषक
आईएस 17717 (भाग 1): 2023 के अनुसार**

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 17717 (Part 1): 2023
	शीर्षक Title	In-Vitro Diagnostic (IVD) Device — Automated Clinical : Chemistry Analyzer Part 1 Wet Chemistry Analyzer
	संशोधनों की संख्या No. of amendments	: Nil
2.	नमूना दिशानिर्देश Sampling Guidelines	
a)	कच्चा माल Raw material	: None
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	: Please refer ANNEX – A
c)	नमूने का परिमाण Sample Quantity	: 1 machine
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 tests as specified in IS 17717 (Part 1) and all routine test specified in Annex F of IS 17724 (Part 1)
6.	लाइसेंस का दायरा /Scope of the Licence:		
*License is granted to use Standard Mark as per <i>IS 17717 (Part 1):2023</i> with the following scope:			
Name of the product		In-Vitro Diagnostic (IVD) Device — Automated Clinical Chemistry Analyzer Part 1 Wet Chemistry Analyzer	
Model(s)			
Type(s)		Fully Automatic / Semi-Automatic	
		Fixed / Portable	
Rating		Rated VoltageV (or) Rated Voltage Ranges(s)V, ac / dc 50 Hz (in case of ac), Single phase / Three Phase, Rated Input Current A, Input powerW (or)kVA	
Protection against electric shock		Class – I / Class – II	
Type of Operation		Continuous / Short-term (or) Intermittent	

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 'In-Vitro Diagnostic (IVD) Device — Automated Clinical Chemistry Analyzer Part 1 Wet Chemistry Analyzer' they intend to cover in the scope of licence.
2. For Grant of Licence/ Change in Scope of Licence, each 'Model' of 'In-Vitro Diagnostic (IVD) Device — Automated Clinical Chemistry Analyzer Part 1 Wet Chemistry Analyzer' is to be tested.
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 In-Vitro Diagnostic (IVD) Device — Automated Clinical Chemistry Analyzer Part 1 Wet Chemistry Analyzer:

- a) Speed (for fully automated) as per Cl. 6.5.2
- b) Method of Calibration as per Cl. 6.4.2 (applicable to the IVD)
- c) Method of estimating results as per Cl. 6.4.3 (applicable to the IVD)
- d) QC Result Plot technique as per Cl. 6.6 (applicable to the IVD)
- e) Degree of ingress protection as per Cl. 11.6 of IS 17724 (Part 1)
- f) Pollution degree
- g) List of essential reagents / accessories (if any)

Note 2: The manufacturer shall also submit the accompanying documents as per Cl. 8 of IS 17717 (Part 1).

ANNEX- B
List of Test Equipment & Documents
Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Power Input, 4.11 and Annex - F	Power Input Test Apparatus/Power Analyzer / Multimeter
2.	Ambient Temperature 5.3	Temperature recorder, AC
3.	Durability of markings, 7.1.3	Distilled water, ethanol 96%, Isopropyl alcohol, Stop watch
4.	Protective earth, Annex - F	Multimeter
5.	Mains Circuits, Annex – F	HV Tester, stopwatch, multimeter
6.	Impedance, 6.4.4	Micro ohm meter, leakage current tester (multimeter)
7.	Protective Conductor Terminal.6.5.2.3	Torque tester
8.	Speed 6.5.2, Method of calibration – 6.4.2, Method of estimating result – 6.4.3, QC result plot technique – 6.6	Reagents

Note 1: The above list is indicative only and may not be treated as exhaustive.

Note 2: The licensee shall maintain a Risk Management File as per the provisions of IS 17724 (Part 1): 2023 for each model in the scope of license.

Note 3: The 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 licensee 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.

- 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;

2.5.2 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 17724 (Part 1): 2023. 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 the model.

2.5.2.2 Licencee shall declare the frequency of periodic review of the Risk Management File to BIS 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 In-Vitro Diagnostic (IVD) Device — Automated Clinical Chemistry Analyzer Part 1- Wet Chemistry Analyzer provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per Cl. 9 and Cl. 7 of IS 17717 (Pat 1): 2023 respectively.

3.2 **Additional Marking requirements:** The material shall also be marked with the following additional requirement on each product and 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				
6	PERFORMANCE EVALUATION, CHARACTERISTICS AND SPECIFICATIONS						
6.1	Sample and Reagent Liquid Handling (Fully Automated Analyzers)						
6.1.1	Sample Volume	6.1.1.1	IS 17717 (Part 1)	R	Each IVD		
6.1.2	Reagent Volume	6.1.2.1	IS 17717 (Part 1)	R	Each IVD		
	Washing (Fully Automated Analyzers)						
6.2.1	Water Remaining in Cuvette	6.2.1.1	IS 17717 (Part 1)	R	Each IVD		
6.2.2	Washing Efficiency	6.2.2.1	IS 17717 (Part 1)	R	Each IVD		
6.3	Photometric Measurement						
6.3.1	Accuracy	6.3.1.1	IS 17717 (Part 1)	R	Each IVD		
6.3.2	Precision	6.3.2.1	IS 17717 (Part 1)	R	Each IVD		
6.3.3	Linearity	6.3.3.1	IS 17717 (Part 1)	R	Each IVD		
6.3.4	Stability	6.3.4.1	IS 17717 (Part 1)	R	Each IVD		
Annex F	Routine Tests (As per IS 17724 (Part 1): 2023						
	General	F.1	IS 17724 (Part 1): 2023	R	Each IVD		
	Protective earth	F.2		R	Each IVD		
	MAINS CIRCUITS			R	Each IVD		
	General	F.3.1		R	Each IVD		
	MAINS CIRCUITS with voltage limiting devices	F.3.2		R	Each IVD		
	Floating circuits	F.4		R	Each IVD		

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5	REQUIREMENTS					
5.1	Safety Requirements	5.1				
	Marking and documentation					
	Marking	5.1	IS 17724 (Part 1)	R	Each IVD	
	General	5.1.1	IS 17724 (Part 1)	R	Each IVD	
	Identification	5.1.2	IS 17724 (Part 1)	R	Each IVD	
	MAINS supply	5.1.3	IS 17724 (Part 1)	R	Each IVD	
	Fuses	5.1.4	IS 17724 (Part 1)	R	Each IVD	
	TERMINALS, connections and operating devices	5.1.5	IS 17724 (Part 1)	R	Each IVD	
	Switches and circuit- breakers	5.1.6	IS 17724 (Part 1)	R	Each IVD	
	Equipment protected by DOUBLE INSULATION or REINFORCED INSULATION	5.1.7	IS 17724 (Part 1)	R	Each IVD	
	Field-wiring TERMINAL boxes	5.1.8	IS 17724 (Part 1)	R	Each IVD	
	Warning markings	5.2	IS 17724 (Part 1)	R	Each IVD	
	Durability of markings	5.3	IS 17724 (Part 1)	R	Each IVD	
	Documentation	5.4	IS 17724 (Part 1)	R	Each IVD	
	General	5.4.1	IS 17724 (Part 1)	R	Each IVD	
	Equipment RATINGS	5.4.2	IS 17724 (Part 1)	R	Each IVD	
	Equipment installation	5.4.3	IS 17724 (Part 1)	R	Each IVD	
	Equipment operation	5.4.4	IS 17724 (Part 1)	R	Each IVD	

	Equipment maintenance and service	5.4.5	IS 17724 (Part 1)	R	Each IVD	
	Integration into systems or effects resulting from special conditions	5.4.6	IS 17724 (Part 1)	R	One	Once in every six months for each type of model manufactured during that period
	Protection against electric shock					
	Determination of ACCESSIBLE parts	6.2	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Limit values for ACCESSIBLE parts	6.3	IS 17724 (Part 1)	S	One	
	Primary means of protection		IS 17724 (Part 1)	S	One	
	ENCLOSURES and PROTECTIVE BARRIERS	6.4.2	IS 17724 (Part 1)	S	One	
	BASIC INSULATION	6.4.3	IS 17724 (Part 1)	S	One	
	Impedance	6.4.4	IS 17724 (Part 1)	S	One	
	Additional means of protection in case of SINGLE FAULT CONDITIONS					
	PROTECTIVE BONDING	6.5.2	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	SUPPLEMENTARY INSULATION and REINFORCED INSULATION	6.5.3	IS 17724 (Part 1)	S	One	
	PROTECTIVE IMPEDANCE	6.5.4	IS 17724 (Part 1)	S	One	
	Automatic disconnection of the supply	6.5.5	IS 17724 (Part 1)	S	One	
	Current- or voltage-limiting device	6.5.6	IS 17724 (Part 1)	S	One	

	Connections to external circuits					Once in every six months for each type of model manufactured during that period
	General		IS 17724 (Part 1)	S	One	
	TERMINALS for external circuits		IS 17724 (Part 1)	S	One	
	Circuits with TERMINALS which are HAZARDOUS LIVE	6.6.3	IS 17724 (Part 1)	S	One	
	Insulation requirements	6.7	IS 17724 (Part 1)	S	One	
	TERMINALS for stranded conductors	6.7.1	IS 17724 (Part 1)	S	One	
	General	6.7.1.1	IS 17724 (Part 1)	S	One	
	CLEARANCES	6.7.1.2	IS 17724 (Part 1)	S	One	
	CREEPAGE DISTANCES	6.7.1.3	IS 17724 (Part 1)	S	One	
	Solid insulation	6.7.1.4	IS 17724 (Part 1)	S	One	
	Requirements for insulation according to type of circuit	6.7.1.5	IS 17724 (Part 1)	S	One	
	Insulation for MAINS CIRCUITS of OVERVOLTAGE CATEGORY II with a nominal supply voltage up to 300 V	6.7.2	IS 17724 (Part 1)	S	One	
	CLEARANCES and CREEPAGE DISTANCES	6.7.2.1	IS 17724 (Part 1)	S	One	
	Solid insulation	6.7.2.2	IS 17724 (Part 1)	S	One	
	Insulation for secondary circuits	6.7.3	IS 17724 (Part 1)	S	One	

	derived from MAINS CIRCUITS of OVERVOLTAGE CATEGORY II up to 300 V					
	General	6.7.3.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	CLEARANCES	6.7.3.2	IS 17724 (Part 1)	S	One	
	CREEPAGE DISTANCES	6.7.3.3	IS 17724 (Part 1)	S	One	
	Solid insulation	6.7.3.4	IS 17724 (Part 1)	S	One	
	Procedure for voltage tests	6.8	IS 17724 (Part 1)	S	One	
	General	6.8.1	IS 17724 (Part 1)	S	One	
	Humidity preconditioning	6.8.2	IS 17724 (Part 1)	S	One	
	The a.c. voltage test	6.8.3.1	IS 17724 (Part 1)	S	One	
	The 1 min d.c. voltage test	6.8.3.2	IS 17724 (Part 1)	S	One	
	The impulse voltage withstand test	6.8.3.3	IS 17724 (Part 1)	S	One	
	Constructional requirements for protection against electric shock	6.9	IS 17724 (Part 1)	S	One	
	General	6.9.1	IS 17724 (Part 1)	S	One	
	Insulating materials	6.9.2	IS 17724 (Part 1)	S	One	
	Colour coding	6.9.3	IS 17724 (Part 1)	S	One	
	Connection to the MAINS supply source and connections	6.10	IS 17724 (Part 1)	S	One	

	between parts of equipment					
	MAINS supply cords	6.10.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Fitting of non-detachable MAINS supply cords	6.10.2	IS 17724 (Part 1)	S	One	
	Cord entry	6.10.2.1	IS 17724 (Part 1)	S	One	
	Cord anchorage	6.10.2.2	IS 17724 (Part 1)	S	One	
	Plugs and connectors	6.10.2.3	IS 17724 (Part 1)	S	One	
	Disconnection from supply source	6.11	IS 17724 (Part 1)	S	One	
	General	6.11.1	IS 17724 (Part 1)	S	One	
	Exceptions	6.11.2	IS 17724 (Part 1)	S	One	
	Requirements according to type of equipment	6.11.3	IS 17724 (Part 1)	S	One	
	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment	6.11.3.1	IS 17724 (Part 1)	S	One	
	Single-phase cord-connected equipment	6.11.3.2	IS 17724 (Part 1)	S	One	
	Disconnecting devices	6.11.4	IS 17724 (Part 1)	S	One	
	General	6.11.4.1	IS 17724 (Part 1)	S	One	
	Switches and circuit-breakers	6.11.4.2	IS 17724 (Part 1)	S	One	
	Appliance couplers and plugs	6.11.4.3	IS 17724 (Part 1)	S	One	

	Protection against mechanical HAZARDS					
	Sharp edges	7.2	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Moving parts	7.3	IS 17724 (Part 1)	S	One	
	Stability	7.4	IS 17724 (Part 1)	S	One	
	Provisions for lifting and carrying	7.5	IS 17724 (Part 1)	S	One	
	Expelled parts	7.6	IS 17724 (Part 1)	S	One	
	Resistance to mechanical stresses					
	General	8.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	ENCLOSURE rigidity tests	8.2	IS 17724 (Part 1)	S	One	
	Static test	8.2.1	IS 17724 (Part 1)	S	One	
	Impact test	8.2.2	IS 17724 (Part 1)	S	One	
	Drop test	8.3	IS 17724 (Part 1)	S	One	
	Protection against the spread of fire					
	General	9.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Eliminating or reducing the sources of ignition within the equipment	9.2	IS 17724 (Part 1)	S	One	
	Containment of fire within the equipment, should it occur	9.3	IS 17724 (Part 1)	S	One	
	Limited-energy circuit	9.4	IS 17724 (Part 1)	S	One	
	Requirements for equipment containing or using flammable liquids	9.5	IS 17724 (Part 1)	S	One	

	Overcurrent protection	9.6	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Equipment temperature limits and resistance to heat					
	Surface temperature limits for protection against burns	10.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Temperatures of windings	10.2	IS 17724 (Part 1)	S	One	
	Other temperature measurements	10.3	IS 17724 (Part 1)	S	One	
	Conduct of temperature tests	10.4	IS 17724 (Part 1)	S	One	
	Resistance to heat	10.5	IS 17724 (Part 1)	S	One	
	Integrity of CLEARANCES and CREEPAGE DISTANCES	10.5.1	IS 17724 (Part 1)	S	One	
	Non-metallic ENCLOSURES	10.5.2	IS 17724 (Part 1)	S	One	
	Insulating material	10.5.3	IS 17724 (Part 1)	S	One	
	Protection against HAZARDS from fluids					
	Cleaning	11.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Spillage	11.2	IS 17724 (Part 1)	S	One	
	Overflow	11.3	IS 17724 (Part 1)	S	One	
	Battery electrolyte	11.4	IS 17724 (Part 1)	S	One	
	Specially protected equipment	11.5	IS 17724 (Part 1)	S	One	
	Specially protected equipment	11.6	IS 17724 (Part 1)	S	One	
	Fluid pressure and	11.7	IS 17724 (Part 1)	S	One	

	leakage					
	Maximum pressure	11.7.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Leakage and rupture at high pressure	11.7.2	IS 17724 (Part 1)	S	One	
	Leakage from low-pressure parts	11.7.3	IS 17724 (Part 1)	S	One	
	Overpressure safety device	11.7.4	IS 17724 (Part 1)	S	One	
	Protection against radiation, including laser sources, and against sonic and ultrasonic pressure					
	General	12.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Equipment producing ionizing radiation	12.2	IS 17724 (Part 1)	S	One	
	Ionizing radiation	12.2.1	IS 17724 (Part 1)	S	One	
	General	12.2.1.1	IS 17724 (Part 1)	S	One	
	Equipment intended to emit radiation	12.2.1.2	IS 17724 (Part 1)	S	One	
	Equipment not intended to emit radiation	12.2.1.3	IS 17724 (Part 1)	S	One	
	Accelerated electrons	12.2.1.4	IS 17724 (Part 1)	S	One	
	Ultraviolet (UV) radiation	12.3	IS 17724 (Part 1)	S	One	
	Microwave radiation	12.4	IS 17724 (Part 1)	S	One	
	Sonic and ultrasonic pressure	12.5	IS 17724 (Part 1)	S	One	
	Sound level	12.5.1	IS 17724 (Part 1)	S	One	
	Ultrasonic pressure	12.5.2	IS 17724 (Part 1)	S	One	
	Laser sources	12.6	IS 17724 (Part 1)	S	One	

	Protection against liberated gases and substances, explosion and implosion					
	Poisonous and injurious gases and substances	13.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Explosion and implosion	13.2	IS 17724 (Part 1)	S	One	
	Components	13.2.1	IS 17724 (Part 1)	S	One	
	Batteries and battery charging	13.2.2	IS 17724 (Part 1)	S	One	
	Implosion of cathode ray tubes	13.2.3	IS 17724 (Part 1)	S	One	
	Components and subassemblies					
	General	14.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Motors	14.2	IS 17724 (Part 1)	S	One	
	Motor temperatures	14.2.1	IS 17724 (Part 1)	S	One	
	Series excitation motors	14.2.2	IS 17724 (Part 1)	S	One	
	Overtemperature protection devices	14.3	IS 17724 (Part 1)	S	One	
	Fuse holders	14.34	IS 17724 (Part 1)	S	One	
	MAINS voltage selection devices	14.5	IS 17724 (Part 1)	S	One	
	MAINS transformers tested outside equipment	14.6	IS 17724 (Part 1)	S	One	
	Printed wiring boards	14.7	IS 17724 (Part 1)	S	One	
	Circuits or components used as TRANSIENT OVERVOLTAGE limiting devices	14.8	IS 17724 (Part 1)	S	One	
	Protection by interlocks					

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	General	15.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Prevention of reactivating	15.2	IS 17724 (Part 1)	S	One	
	Reliability	15.3	IS 17724 (Part 1)	S	One	
	HAZARDS resulting from application					
	REASONABLY FORESEEABLE MISUSE	16.1	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period Testing and assessment of the product to be done as specified in the Risk assessment documentation
	Ergonomic aspects	16.2	IS 17724 (Part 1)	S	One	
	RISK assessment	17	IS 17724 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period to ensure that the risks have been eliminated or that only tolerable risks remain
5.2	EMC Requirements		IS 17784 (Part 2)/IEC 61326-2-6	S	One	Once in every three years for each type of model manufactured during that period