PRODUCT MANUAL FOR OPHTHALMIC INSTRUMENTS — PERIMETERS ACCORDING TO IS 18291: 2023

उत्पाद मैन्यूअल नेत्र सम्बन्धी उपकरण - पेरीमीटर आईएस 18291: 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 18291: 2023
	शीर्षक **Title**	:	Ophthalmic Instruments — Perimeters
	संशोधनों की संख्या **No. of amendments**	:	Nil
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चामाल** **Raw material**	:	None
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**	:	Please refer **ANNEX – C**

	Testing		
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**	:	• All type tests as specified in Cl 5.7
6.	**लाइसेंस का दायरा /Scope of the Licence:**		

"License is granted to use Standard Mark as per ***IS 18291: 2023*** with the following scope:		
Name of the product		Ophthalmic Instruments — Perimeters
Model(s)		
Type	**Based on movement of test stimuli**	Kinetic Perimeter (Automatic control / Manual Control) / Static Perimeter
	Based on position of test stimuli	Fixed – location based stimulus Perimeter / Projection based Stimulus Perimeter
Type of instrument		Active Ophthalmic instrument / Non-active Ophthalmic instrument
Rating (Only for Active Ophthalmic Instrument)		Rated Voltage …..V (or) Rated Voltage Ranges(s) ……V, ac Frequency …. Hz, Single phase / Three Phase, Rated Current …. A, Input power …….W (or) ….kVA
Software Driven		With / Without
Optical Radiation Hazard		With / Without

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 'Ophthalmic Instruments — Perimeters' they intend to cover in the scope of licence.

2. For Grant of Licence/ Change in Scope of Licence, each 'Model' of 'Ophthalmic Instruments — Perimeters' 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 1: Firm shall declare the following parameters for each of the Model of Ophthalmic Instruments — Perimeter:

a) Background luminance, L_B
b) Contrast, $\Delta L/L_B$
c) Stimulus location
d) Stimulus size
e) Stimulus duration
f) Extent of background
g) Degree of ingress protection
h) Pollution degree
i) List of essential accessories

Note 2: The manufacturer shall also submit the accompanying documents as per Cl.6 of IS 18291: 2023.

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.	Checking the background luminance – Cl.5.1, Checking Stimulus luminance – Cl. 5.2	Luminance Meter /
2	Checking the test stimulus location, size and shape – Cl.5.3, Cl.5.4, Cl.5.5	Vernier Caliper, Measuring Tape
3	Checking the test stimulus duration – Cl.5.6	Stop watch

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/ISO 15004 (Part 1): 2020 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 Control 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 Control system 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 2.5.

1.3 **RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT**:

1.3.1 As mentioned above, recommended levels of control are given in **Table 1 for guidance only**.

1.3.2 The tests as indicated in Table 1 and at the levels of control in column 3 of Table 1 or the Quality Assurance Plan as submitted by the manufacturer to BIS may be carried out on the whole production of the factory which is covered by this plan and records maintained in accordance with para 2.5.

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 where test equipment is required in house i.e "R" or whether it can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

2.2 **For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility is 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 (including foreign manufacturers) shall maintain an in-house laboratory,** which shall be suitably equipped (as given in column 2 of Table 1) and staffed, 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 test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, these manufacturers can also utilize the provisions of Sharing of testing facilities as per the Annexure-X (Relaxation in test facilities) of the guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process)

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 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 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 licencee 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.

2.5.1.3 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;

2.5.2 RISK MANAGEMENT FILE- The licencee shall maintain a Risk Management File for each model in the scope of licence as per the requirement of IS/ISO 15004 (Part 1): 2020. 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 licencee 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 Ophthalmic Instruments — Perimeters provided always that the material so marked conforms to each requirement of the specification.

3.1 Marking shall be done as per Cl. 7 of IS 18291: 2023.

3.2 **Additional Marking requirements**: The following additional requirements shall also be marked on the packing of each Ophthalmic Instrument - Perimeters:

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**				
	Materials	4.5.1 4.5.2	IS 18638 (Part 1)	S	One	Each Consignment	No further testing is required is accompanied with test certificate
4	**Requirements**						
4.2	Specific requirements	4.2.1 & Table 1 4.2.2 4.2.3 4.2.4 4.2.5 4.2.6 4.2.7 4.2.8 4.2.9 4.2.10 Table 2 & Table 3 4.2.11 4.2.12	IS 18291	R	Each Perimeter		
4.3	Kinetic Perimeter	4.3.1 4.3.2	IS 18291	R	Each Perimeter		
4.4	Static Perimeter	4.4.1 4.4.2	IS 18291	R	Each Perimeter		
	General						
	Design	4.2	IS 18638 (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 reduced to level compatible with the generally acknowledged state of the art
	Performance	4.3	IS 18638 (Part 1)	R	Each Perimeter	
	Combination of different devices	4.4	IS 18638 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Protection against contaminants	4.6	IS 18638 (Part 1)	R	Each Perimeter	
	Scales and displays	4.7	IS 18638 (Part 1)	R	Each Perimeter	
	Thermal hazards	4.8	IS 18638 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Mechanical hazards	4.9	IS 18638 (Part 1)	S		
	Particular requirements for active Perimeter					
6.1	**Electrical Safety**					
	General requirements					
	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS and ESSENTIAL PERFORMANCE	4.2	IS 13450 (Part 1)	R	Each Equipment	
	ESSENTIAL PERFORMANCE	4.3	IS 13450 (Part 1)	R	Each Equipment	
	Conditions for application to ME EQUIPMENT or ME SYSTEMS	4.1	IS 13450 (Part 1)	R	Each Equipment	
	Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS	4.5	IS 13450 (Part 1)	R	Each Equipment	
	ME EQUIPMENT or ME SYSTEM parts that contact the	4.6	IS 13450 (Part 1)	R	Each Equipment	

	PATIENT					
	SINGLE FAULT CONDITION for ME EQUIPMENT	4.7	IS 13450 (Part 1)	R	Each Equipment	
	Components of ME EQUIPMENT	4.8	IS 13450 (Part 1)	R	Each Equipment	
	Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT	4.9	IS 13450 (Part 1)	R	Each Equipment	
	Power Supply					
	Source of power for ME EQUIPMENT	4.10.1	IS 13450 (Part 1)	R	Each Equipment	
	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS	4.10.2	IS 13450 (Part 1)	R	Each Equipment	
	General requirements for testing ME EQUIPMENT	5.1 to 5.7	IS 13450 (Part 1)	R	Each Equipment	
	Determination of APPLIED PARTS and ACCESSIBLE PARTS	5.9	IS 13450 (Part 1)	S	One	
	ME EQUIPMENT identification, marking and documents	7.2 to 7.8.2 Annex C	IS 13450 (Part 1)	R	Each Equipment	
	Energy consumption (power input)	4.11	IS 13450 (Part 1)	R	Each Equipment	
	Limitation of voltage, current or energy	8.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Separation of parts	8.5.1 to 8.5.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	CREEPAGE DISTANCES and AIR CLEARANCES	8.9	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period

	Serviceability	15.2	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Accuracy of controls and instruments and protection against hazardous outputs	12.1 12.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT	11.8	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Protective earthing, functional earthing and potential equalization of ME EQUIPMENT	8.6	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Excessive temperatures in ME EQUIPMENT	11.1	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength at steady-state operating temperature	8.4.2 8.7 8.8.3	IS 13450 (Part 1)	R	Each Equipment	
	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength after humidity preconditioning at ambient temperature in the laboratory	8.4.2 8.7 8.8.3	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	HAZARDOUS SITUATIONS and	13	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period

	fault conditions					
	MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5	15.5	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	ME EQUIPMENT components and general assembly	15.4 8.10	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	MAINS PARTS, components and layout	8.11	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Insulation other than wire insulation	8.8.4	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Fire prevention and constructional requirements for fire ENCLOSURES of ME EQUIPMENT	11.2 11.3	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	Overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT	11.6	IS 13450 (Part 1)	S	One	Once in every six months for each type of model manufactured during that period
	VERIFICATION of markings	7.1 7.2 to 7.8.2 Annex C	IS 13450 (Part 1)	R	Each Equipment	
	EMC Requirements		IS 13450 (Part 1/ Sec 2)	S	One	Once in every three years for each type of model manufactured during that period

6.2	Optical radiation hazard		IS 18638 (Part 2) / ISO 15004 (Part 2)	S	One	Once in every six months for each type of model manufactured during that period