BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Sectional Committee	Meeting No	Date, Day & Time
Ophthalmic Instruments and Appliances SectionalCommittee, (MHD 05)	19th	09 December 2024, Monday, 3:00 PM

via Webex platform
Meeting Link:
https://bismanak.webex.com/bismanak/j.php?MTID=m3c7a7b2099c19c36226c964c8996c4aa

Meeting Number: 2519 008 0502

Password: Mhd05@19

Venue: Sri Sairam Engineering College, Chennai

Chairperson	Prof. (Dr.) Jolly Rohatgi Professor and HOD Department of Ophthalmology University College of Medical Sciences, New Delhi
Member Secretary	Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

0.2 OPENING REMARKS BY CHAIRPERSON

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

1.1 The minutes of the Eighteenth meeting of the Ophthalmic Instruments and Appliances Sectional Committee, (MHD 05) held on 02nd September 2024 approved by the Chairperson and circulated to all members through the BIS portal as well as email vide letter no: MHD05/A2.18 dated 12- Sep-2024.

1.2 No comments have been received so far.

The Committee may formally confirm the minutes.

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

2.1 The present scope of the Ophthalmic Instruments and Appliances Sectional Committee (MHD 05) is as follows:

1. To formulate Indian Standards for Ophthalmic Diagnostic, Examining, Surgical devices, and Instruments including Ophthalmic wear and vision care products excluding products for persons with visual disability; and
2. To coordinate with the work of:

- ISO/TC 172/ SC 7 Ophthalmic Optics and Instruments (P Member)
- ISO/TC 172/SC 9/WG 4 Laser systems for medical applications (P Member)

The Committee may please note.

2.2 The following Nomination received for co-option request:

Sl. No.	Organisation	Nomination
1.	Individual Capicity	Amitesh Kumar
2.	Baxter R&D, Bengaluru	Hari Babu S

Note: Nomination CVs are attached in ***Annexure A***

The Committee may kindly deliberate and approve.

2.3 The present composition of Ophthalmic Instruments and Appliances Sectional Committee (MHD 05) with participation status of members is enclosed at ***Annexure B***

2.4 With a view to make the Committee more effective through active contribution of the members in standardization activities, non-participating members are liable to be dropped from the Committee in order to provide opportunity to other similar organizations/institutions that may be interested to participate and contribute to the standardization efforts. Further, the Committee needs to be made fully representative of the various interests concerned consideringthat non-industry representation should not be less than two-third of the committee composition, as far as possible.

The committee may please note and review the composition.

2.5 The following working panel are constructed in MHD 05:

a) Spectacle frames and spectacle lenses

Sr. No	Name	Role
1.	Dr. Balachandra settu	Convener
2.	Dr. Dattatraya hegde	Expert
3.	Mr. B. Shankar	Expert
4.	Mr. Sandeep reddy	Expert

b) Ophthalmic Implants and Contact lenses.

Sr. No	Name	Role
1.	Mr. R. Krishna Kumar	Convener
2.	Mr. Shankar Balasubramanian	Expert
3.	Ms.Kanimozhi	Expert
4.	Mr. Gowardhan	Expert

c) Ophthalmic Devices (Diagnostic and surgical electromedical devices)

Sr. No	Name	Role
1.	Mr. Rathinam Thyagarajan	Convener

d) Ophthalmic surgical instruments.

Sr. No	Name	Role
1.	Mr. Narendra Kumar Jain	Convener
2.	Mr. Kuldeep Sharma	Expert

The Committee may kindly note.

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

3.1 The following draft of the Indian Standard Amendment has been sent for wide circulation:

Sl. No.	**Document No.**	**Title**	**Last date for comments**	**Comments received (Yes/No)**
1.	MHD/05/26614	Ophthalmic implants - Intraocular lenses: Part 4 labelling and information Amendment - 1	16-Oct-2024	No

The Committee may kindly approve.

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

4.1 The following draft document had been circulated as a preliminary draft:

Sl. No.	Document No.	Title	Last date for comments	Comments received (Yes/No)	Remark
1.	MHD/05/26784	Sterile Blades for Ophthalmic Microsurgeries for Single Use-Requirements and Test Methods	21-Oct-2024	No	Indigenous

The Committee may kindly approve.

4.2 As per the 18th meeting committee, The Committee deliberated and decided to circulate the Following draft document for 30 days.

Sr. No	Title	Comments Received	Draft Document attached
1.	Ophthalmic Scan A and B	Prof. Jolly Rohtangi is clause 4.2.9 and clause 4 & 5	Draft document , attached given ***Annexure C***

The Committee may kindly deliberate.

4.3 The comments on WC drafts shall be made only through the Standardization Portal. The BIS portal provides a very user friendly interface and helps faster compilation and analysisof comments. In case of any difficulties in accessing the portal, the members may contact the Member Secretary for necessary guidance.

The Committee may kindly note.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The new Indigenous Subject was taken up for the standard formulation :

Sr. No	Subject
1.	Donor Cornea Container

Note: The committee may kindly nominate the expert for the subject.

The Committee may kindly deliberate.

5.2 Commenting on P-Drafts by Members of Technical Committee

5.2.1 P-Draft is the stage where members of the concerned technical committee can supportor reject the project or offer comments for improvement. Therefore, abstaining from commenting on the P-Draft by a member has serious implications on the quality of the draft. BIS had issued directions regarding commenting on P-Drafts wherein any member not commenting on two consecutive and/or one-fourth of the P-Drafts circulated by the TechnicalCommittee in a year will automatically be disqualified to continue as a member.

5.2.2 The members may examine the P-Draft document(s) whenever under circulation andoffer comments as per the following options:

(a) Agree
(b) Agree (with comments*)
(c) Don't agree (with comments*)
(d) No Comments, as it is not related to my area of expertise.

5.2.3 The comments on P- Drafts shall be made only through the Standardization Portal.

The Committee may kindly note.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 No comments have been received on published Indian Standards.

The committee may kindly note.

ITEM 7 NEW SUBJECTS

7.1 The committee may identify the emerging fields in the area under its scope and decide formulation of Indian Standards on the same. The Committee may also define thrust area, whichshould take into consideration the standards development required in the given context keepingin view the social, environmental and economic consideration.

The Committee may kindly deliberate.

7.2 List of ophthalmic devices notified by CDSCO that are mapped with respect to available Indian Standards are given in ***Annexure D*** Committee Members have to go through the list of products and suggest the subjects where standards are to be formulated on priority.
The Committee may kindly deliberate and decide.

ITEM 8 TECHNICAL ISSUES

There are no specific technical issues to be discussed.

The Committee may kindly note.

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 BIS participates in the International Standardization activities of the International Organization for Standardization (ISO) thereby contributing to International Standards development activities. It is a constant endeavor of the Sectional Committees to identify priority areas for participation in International technical committees that are of strategic importance to India and to identify relevant experts who would actively contribute to international standardization. The details of membership held in various Technical Committees/Subcommittees of ISO are given below:

Sl. No	**Liaison Committee of ISO**	**Type of Membership**
1.	ISO/TC 172/SC 7 Ophthalmic Optics and Instruments	Participating Member
2.	ISO/TC 172/SC 9 Laser and electro-optical systems	Participating Member

Sl.	**REFERENCE**	**TITLE**
1	ISO/TC 172/SC 7/WG 2	Spectacle frames
2	ISO/TC 172/SC 7/WG 3	Spectacle lenses
3	ISO/TC 172/SC 7/WG 6	Ophthalmic instruments and test methods
4	ISO/TC 172/SC 7/WG 7	Ophthalmic implants

9.1.2 As a P-member, it is mandatory for India (BIS) to vote on all draft standards and otherdocuments circulated by ISO seeking votes/comments. The members should carefully examinethe documents taking into consideration nation's interests and send the comments to BIS keeping in mind that if these ISO Standards so finalized are adopted as Indian Standards in future, the Indian Medical Device Industry would not have any problem in its implementation.The experts who are not contributing to international standardization by submitting comments/feedback on work items and ballots will not be allowed to represent BIS (India) in ISO/ IEC Technical meetings.

The Committee may kindly note.

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 Working Groups (WGs) are established by ISO/IEC Technical Committees for specifictasks. The Experts are nominated in these WGs by BIS ('P' Member National Standards Body NSB) to deal with specific tasks allocated to the Working Group. Persistently Inactive Experts, meaning the absence of contributions through attendance to WG meetings or by correspondence, will be removed from the Working Groups by ISO Technical Committee. This removal of Inactive Experts would also reflect badly on the 'P' Member NSB. Therefore, participation of nominated Indian Experts at the Working Group level of ISO is of critical importance while being a part of BIS for Standards Development.

9.2.2 The nomination of above members as 'Expert' to ISO Working Groups has been considered by BIS based on the recommendations of the Sectional Committee taking into account that he/she would actively participate in the projects concerned. By accepting an appointment as an Expert, the respective members are committing to actively participate in theWorking Group to which he/she is appointed and to fulfill the obligations associated with participation. The Working Group Experts are also required to inform the National Mirror Committee (i.e the concerned BIS Technical Committee that has the liaison with the ISO Technical Committee) of their contribution and progress of the work. The level of contributionof the nominated Working Group Experts may be reviewed and decision may be taken regarding continuation/ termination of nomination.

The Committee may kindly consider.

9.2.3. The list of nominated experts for ISO projects is attached in *Annexure E.*

The committee may kindly note.

9.3 Harmonization of Indian Standards with International Standards

9.3.1 The list of Standards published by the TCs and SCs of ISO/ TC 172/SC 7 alongwith their status of adoption is given in ***Annexure F***

ITEM 10. PROGRAMME OF WORK

10.1 The present Programme of Work of Ophthalmic Instruments and Appliances SectionalCommittee (MHD 05) is available at BIS website www.bis.gov.in.

The Committee may kindly note.

10.2 The progress of the development of Indian Standards at various stages is given below:

Stage	No. of Documents
Under Print	**07**

Sl. No	Document No	Title
1.	MHD/05/25356	Ophthalmic instruments - Direct ophthalmoscopes
2.	MHD/05/25281	Ophthalmic optics - Mounted spectacle lenses
3.	MHD/05/25357	Ophthalmic instruments - Indirect ophthalmoscopes
4.	MHD/05/25337	Ophthalmic optics - Spectacle lenses -Vocabulary
5.	MHD 05 (25458)	Ophthalmic optics -Uncut finished spectacle lenses Part 3 Transmittance specifications and test methods(First Revision)
6.	MHD/05/25340	Ophthalmic optics Contact lenses and contact lens care products Labelling
7.	MHD/05/25343	Ophthalmic optics - Contact lenses and contact lens care products Fundamental requirements

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 As per the policy of the Indian Standards published before the year 2000 need to be reviewed for Revision/withdrawal/archived in the light of technological developments that have happened so far in relation to these standards. ***Annexure G***

The Committee may kindly deliberate and approve.

11.2 Review of Standards as per 5-year cycle

11.2.1 As per the policy of BIS, the Indian Standards which have completed five yearssince their last publication/reaffirmation, are to be reviewed by the concerned Sectional Committee for their reaffirmation/revision/withdrawal/amendment/archiving in the light of technological developments that have happened so far in relation to these standards.

11.2.2 With a view to improve the quality of standards formulation process and making it more evidence based, BIS envisions to undertake research and prepare a review document inrespect of each of the Indian Standards which are due for revision.

11.2.3 The list of such Indian Standards which are due for review in **FY 2025-2026** isgiven at ***Annexure H.***

The Committee may kindly deliberate and decide further course of action.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

There are no specific issues to be discussed.

The Committee may kindly note.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2023-24, the next meeting of MHD05 is scheduled on 10th March 2025.

Quarter	**Q1** (April-June)	**Q2** (July-September)	**Q3** (October-December)	**Q4** (January March)
Date	13th May 2024 (Monday)	2nd September 2024 (Monday)	9th December 2024 (Monday)	10th March 2025 (Monday)

The Committee may kindly note.

ITEM 14 ANY OTHER BUSINESS

14.1 Review of the working group (Amendment Working Group for Indian Standard)

As per the 18th meeting discussion Amendment working group meetings were conducted:

	Meeting No	Date	Agenda and Minutes
I.	1st Amendment Working Group for Indian Standard	24th Oct 2024	Annexure I

The committee may kindly note.

BIO-DATA

Summary:

Dr. Amitesh Kumar has been working in the area of semiconductor devices for applications in Memory, Solar Cells, Biosensors, Power Electronics etc, since 2014.

He has **36 SCI journals** with **4 Patents** (**2 granted**, 2 published) along with 12 International and 24 National conferences papers and 11 book chapters. **2 PhD students** have submitted thesis under his guidance. **1 DST project of 29 Lacs** running and 2 ISRO projects in communication. List of Publications is attached.

His works have been published in reputed SCI journals, including 6 works on IEEE Transactions**.** Recently, one of his works on synaptic devices was accepted in IEEE Transactions on Electron Devices. **Device Engineering of Dual Metal Gate-based Artificial Synapse for Enhanced Plasticity utilizing Al2O3 based Ion Conducting Electrolyte.**

Dr. Amitesh Kumar has done his B.Tech in Electrical Engineering from **Indian Institute of Technology, BHU** .He did his Ph.D. in Electrical Engineering from **Indian Institute of Technology, Indore**. He did his Postdoc Research from **University of Utah, USA** and **Indian Institute of Technology, Kanpur.**

He has been a Research Fellow awardee from **CSIR, Govt. of India**. He is currently working as Assistant Professor in Electrical Engineering at National Institute of Technology, Patna.

He has been awarded SCJP, CCNA, CCNP, ACP by respective organisations. He has also been recipient of multiple research awards for Best Presentation, DST & CSIR International Travel Support etc.

Research Interests:

Semiconductor devices for applications in Memory, Solar Cells, Biosensors, Power Electronics Neuromorphic Computing

1. ***Name and full correspondence address with contact details***

Dr. Amitesh Kumar

Assistant Professor, Electrical Engineering
National Institute of Technology (NIT), Patna, India

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: +91-8349287043 (India), +1-385-955-8446 (USA)
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ResearchGate: https://www.researchgate.net/profile/Amitesh_Kumar10/research?ev=prf_act

Google Scholar: https://scholar.google.co.in/citations?user=lIQ7ERIAAAAJ&hl=en&authuser=2

ORCID ID : https://orcid.org/0000-0003-1315-3922

2. *Institution* : *National Institute of Technology (NIT), Patna, India*

3. *Academic Qualification*

- **Education**

S/N	Degree	Year	Subject	University/ Institution	% of Marks
1.	B. Tech	May, 2009	Electrical Engineering	Indian Institute of Technology, BHU	CPI 7.4

B. Tech Project title: *Study of Cluster Based Routing Protocol for Mobile Adhoc Networks (MANETS) And performance comparison of pro-active and reactive protocol*

Name of Project Supervisor (s) and his affiliation

1. **Prof. S.C. Gupta, Electrical Engineering, IIT-BHU**
   scgupta.eee@iitbhu.ac.in, scgupta_bhu@yahoo.com
   https://www.researchgate.net/profile/Suresh_Gupta5

2.	XII	May, 2004	English, Mathematics, Physics, Chemistry	BSEB	73.8 %
3.	X	May, 2002	English, Hindi, Mathematics, Science, Social Science, Computer studies	ICSE	92.6 %

8. *Ph.D thesis title, Guide's Name, Institute/Organization/University, Year of Award.*

S/N	Degree	Year	Subject	University/ Institution	% of Marks
1.	Ph. D.	May, 2019	Electrical Engineering	Indian Institute of Technology, Indore	CPI 7.82

Ph.D thesis title: *Fabrication and modelling of ZnO based resistive switching devices for non-volatile memory applications*

Name of Thesis Supervisor (s) and their affiliation

1. **Dr. Shaibal Mukherjee, Electrical Engineering, IIT Indore**
   shaibal@iiti.ac.in
   http://www.iiti.ac.in/people/~shaibal/leader.php

2. **Prof. Abhinav Kranti**, **Electrical Engineering, IIT Indore**
   akranti@iiti.ac.in
   http://people.iiti.ac.in/~akranti/

9. *Work experience (in chronological order).*

- **Industrial Experience**

Positions held	Name of the Institute	From	To	Pay Scale
1. Software Engineer	Verizon Data Services India (VDSI)	12-08-2009	03-12-2010	6.5 lacs per annum

Role & Responsibilities: Data-mining for Fios TV (Verizon, USA) for targeted marketing, implementing Lua scripts for Fios TV, web-services and web development/management

- **Entrepreneurship Experience**

	Positions held	Name of the Institute	From	To	Pay Scale
1.	**Senior Analyst**	Vihar IT Solutions Pvt. Ltd.	03-03-2011	30-07-2013	Owner of company

Role & Responsibilities: Entrepreneurship experience, Company management, Technical consultancy for software and web solutions

- **Research Experience**

	Positions held	Name of the Institute	From	To	Pay Scale
1.	**CSIR, Junior Research Fellow (JRF)**	Indian Institute of Technology (IIT) Indore	22 July 2014	July 2016	INR 25000.00 per month + HRA

Role & Responsibilities: Deposition & characterization of micro- and nano-structured materials, and to apply this knowledge in realizing advanced tools and devices

2.	**CSIR, Senior Research Fellow (SRF)**	Indian Institute of Technology (IIT) Indore	July 2016	Jan 2019	INR 28000.00 per month + HRA

Role & Responsibilities: Experimental fabrication, characterization, and modelling of RRAMs/Memristor for the application of non-volatile memory and neuromorphic applications

3.	**Postdoc Research Scientist**	University of Utah USA	Jan 2019	Sep 2019	USD 55,000 per annum

Role & Responsibilities: Broadly doing research related to emerging device technologies, digital design, and design automation and specifically utilizing Non-Volatile Memories (NVMs) like Resistive Random Access Memory (RRAM) in reconfigurable logic circuits, such as Field-Programmable Gate Arrays (FPGAs)

4.	**Postdoc Research Scientist**	Indian Institute of Technology Kanpur	Sep 2019	Feb 2020	INR 70000 per month

Role & Responsibilities: Optimization of various parameters of solar cells and corresponding modelling to analyze various performance parameters.

- **Academic Experience**

	Positions held	Name of the Institute	From	To	Pay Scale
1.	**Assistant Professor**	National Institute of Technology (NIT) Patna	Feb 2020	Till Present	Grade Pay, Level 11

Role & Responsibilities: Teaching and supervising laboratories of several subjects at Electrical Engineering Dept. as well working as in-charge of several institutional/departmental responsibilities and carrying out research in concerned field.

10. *Professional Recognition/ Award/ Prize/ Certificate/Fellowship received by the applicant.*

- **Research Awards**

1. **DST International Travel Support** to attend and present paper in *20th International Conference on Superlattices, Nanostructures and Nanodevices (ICSNN2018), Madrid, Spain, July 23-26, 2018*

2. **Best Presentation award**, *6th International Symposium on Integrated Functionalities***,** *December 10-13***,** *2017*

3. **CSIR International Travel Support** to attend and present paper in *Materials Research Society (MRS) Spring Meeting, Phoenix, Arizona, USA, April 2-6, 2018*

4. **MPCST International Travel Support** to attend and present paper in *34th International Conference on the Physics of Semiconductors (ICPS 2018), Montpellier, France, 2018*

5. **Indian Institute of Kanpur, Institute Postdoc Fellowship Award** to carry out research in Materials Science and Engineering Dept. for two years

6. **DST National Postdoc Fellowship Award 2020**

➢ Academic Achievements

	Name of Award	Awarding Agency	Year
1.	**Autodesk Certified Professional (ACP) (Score: 957/1000, Certiport ID: 90065872)**	*Autodesk*	*2018*
2.	**Senior Research Fellowship**	*CSIR*	*2016- 19*
3.	**Junior Research Fellowship**	*CSIR*	*2014-16*
4.	**CSIR Fellowship award**	*CSIR*	*2014*
5.	**Sun Certified Java Programmer (SCJP) (Score: 90 %, Candidate ID: SR3198768, Registration ID:PC0SYD5218)**	*Sun Professional*	*2008*
6.	**Cisco Certified Network Associate (CCNA) (Score: 947/1000 in Exam 640-802, Cisco ID: CSCO11459282; Registration ID: 226180540)**	*Cisco*	*2008*
7.	**Cisco Certified Network Professional (CCNP), BSCI & BCMSN (Score: 981/ 1000 in Exam 642-892)**	*Cisco*	*2008*

➢ Certification Courses completed

	Name of Award	Awarding Agency	Year
1.	**Reliability Engineering and Asset Management**	*Global Initiative of Academic Networks (GIAN), MHRD, India*	*2018*
2.	**Media Security and Forensics**	*Global Initiative of Academic Networks (GIAN), MHRD, India*	*2018*
3.	**Energy, Education, and Innovation**	*Global Initiative of Academic Networks (GIAN), MHRD, India*	*2018*
4.	**Advanced Pattern Recognition Techniques for Biometrics**	*Global Initiative of Academic Networks (GIAN), MHRD, India*	*2018*
5.	**Fundamentals of Solid State Physics: From Theoretical and Computational Concepts to Recent Applications in Information Technology**	*Global Initiative of Academic Networks (GIAN), MHRD, India*	*2018*
6.	**Economics of Science, Technology and Innovation: Empirical Approaches and Randomized Control Trials (RCTs)**	*Global Initiative of Academic Networks (GIAN), MHRD, India*	*2018*

7. **Inorganic chemistry of imaging: Magnetic resonance and optical imaging with coordination complexes** — *Global Initiative of Academic Networks (GIAN), 2018 MHRD, India*

8. **Computationally Aided Materials Designing for Materials Genome** — *Global Initiative of Academic Networks (GIAN), 2018 MHRD, India*

11. Projects

- **Projects**

	Project Title	Sponsoring Agency Institute	From	To	Amount
1.	Bio-inspired Electronic Synaptic Cells for Neuromorphic and Bio-medical applications	DST-SERB	Feb 2022	Till now	INR 28.5 Lakhs

[File No: SRG/2021/002110]

Project Highlights: The project works towards designing high-speed, high-density, highly-scalable, energy-efficient electronic synaptic cells, which can be utilized primarily for data storage and neuromorphic applications. It aims to identify and design an emerging non-volatile memory (NVM) technology, i.e., Memristor or Resistive Random Access Memory (RRAM) in the form of functional hybrid Memristor Crossbar-Array/CMOS System

2.	DST Training Program on Entrepreneurship	DST	July 2021	Till Now	INR 3.6 Lakhs

Project Highlights: DST Training Program on Entrepreneurship through Innovation and Entrepreneurship Division and Training Program on Entrepreneurship Scheme

13. *Any other Information (maximum 500 words)*

- **Internship/training**

	Name of company	Purpose	Year
1.	**Jetking Newdelhi**	*To install, configure, operate, and troubleshoot medium-size routed and switched networks, including implementation and verification of connections to remote sites in a WAN(wide area network)*	*2006*
2.	**Uttar Pradesh Power Corporation Limited (UPPCL), Azamgarh**	*Summer training at a sub-station of UPPCL, Azamgarh for around eight weeks*	*2009*

- **Technical workshop/events attended/invited**

	Name of Workshop/Events	Organizing Agency	Year
1.	**Engineering Education & Research Seminar, Radisson Blu Indore, India November 27, 2017 (Invited)**	*National Instruments*	*2017*
2.	**Friends of MP Conclave, Hotel Marriott, Indore, Jan. 3-4 2018 (Invited)**	*Govt. of Madhya Pradesh, India*	*2018*
3.	**18th International Workshop on The Physics of Semiconductor Devices (18th IWPSD), IISc, Bangalore, India, December 7-10, 2015**	*IWPSD*	*2015*

- **Social activities**

	Name of Award	Awarding Agency	Year
1.	**Rashtriya Avishkar Abhyan, Teaching Portal**	*Ministry of Human Resource and Development*	*2016*
2.	**Swachh Bharat Summer Internship 2018 Summer Internship**	*Unnat Bharat Abhiyan*	*2018*

- **Extra-curricular activities**

	Name of Award	Awarding Agency	Year
1.	**Yoga Therapy certification**	*DAVV, Govt. of Madhya-Pradesh*	*2018*
2.	**4th Edition Indore Marathon, 10 km**	*Academy of Indore Marathoners*	*2018*
3.	**Lotus 10k Run 2018**	*Indore Super Chargers*	*2018*
4.	**Cycle Marathon 50 km , 2018**	*Youjustrun*	*2018*

- **Affiliation to Professional Organizations**

	Name of Organization	Affiliation status
1.	**IEEE**	*Member (94148943)*
2.	**Indian Laser Association**	*Life Member (LM-1262)*
3.	**VIBHA (Vijnana Bharati)**	*Life Member (21101)*
4.	**Plasma Science Society of India (PSSI)**	*Life member (LM-1542)*
5.	**The Institute of Engineers (India)**	*Chartered Engineer (AM1839643)*
6.	**Indian Science Congress Association, ISCA, India**	*Life Member (L37164)*
7.	**Material Research Society, USA**	*Member (phd1401102003)*

- **Technical reviewer in journals**

	Name of journal
1.	**IEEE: Transactions on Nanotechnology**
2.	**AIP: Applied Physics Letters**
3.	**IEEE: Transactions on Computer-Aided Design of Integrated Circuits and Systems**
4.	**IET: Circuits, Devices & Systems**
5.	**Wiley : Advanced Electronics Materials**
6.	**Elsevier : Superlattices and Microstructures**

7. **AIP: Journal of Applied Physics**

- **Scientific contributions in magazines**

Name of Magazine

1. **Brainfeed Higher Education Plus**

- **Nanodevice fabrication/processing/characterization/modelling expertise**

1. **Device fabrication techniques**
   a) Dual Ion Beam Sputtering (DIBS), b) Electrodeposition, c) Hydrothermal method d) Spin-coating

2. **Device processing methods**
   a) Rapid Thermal Processing (RTP) Annealing

3. **Device characterization instruments hands-on**
   a) Keithley 4200A-SCS Parameter Analyzer, b) Keithley 2612A Sourcemeter, c) B1500 Keysight, d) Hioki 3532–50 LCR Hi-Tester, e) Variable-angle/wavelength Spectroscopic Ellipsometry, f) Cryogenic Vacuum Probe-station, g) Quantum Efficiency Measurement System, h) Solar Simulator System.

4. **Device modelling software experience**
   Matlab, COMSOL, Silvaco, Orcad-PSPICE, Quantum espresso

5. **Designing masks for semiconductor devices**
   AUTOCAD

6. **Device design (Digital design) and automation**
   PSPICE

7. **Device (Wafer/die) packaging**
   Wire-bonding (MEI1204W)

8. **Device (Wafer/die) testing**
   Probe-card (GGB), Probe-station, B1500 Semiconductor Device Parameter Analyzer

- **Other technical skills**

1. **Software skills**
   C, Data Structure, Core Java (SCJP 5.0) J2EE(servlets, jsp), C#.net

2. **Website building**
   PHP, Javascript, Asp.net, HTML

3. **Database management system**
   Sql-server 2008

4. **Networking**
   LAN management
   1. Routing: Routing protocols (RIP, EIGRP, OSPF, BGP), IP multicast design models
   2. Switching : Campus network model, STP ,VLAN ,multilayer switching, switch security

   WLAN management
   Access Points (AP), Lightweight AP operation, AP association and roaming

Important Research Achievements

1. **Using cost-effective Al electrode against expensive Pt electrodes to give Non-volatile Memory (NVM) Solution**
2. **Evading the process of electroforming in RRAM using material engineering methods to give high-performance NVMs**
3. **Universal and novel analytical model of RRAM to design RRAMs using wide range of switching materials and electrodes**
4. **Creating a Cluster-Based Routing Protocol for Mobile Adhoc Networks (MANETs) to establish adhoc networks in any isolated area devoid of network infrastructure**
5. **Organic material based RRAM device to give an eco-friendly Non-Volatile Memory (NVM) solution**

Organizing important research seminar, workshop etc.

1. FDP course **"Next-Generation Semiconductor Devices for high-end applications " (22nd-27th June 2020) was organized at Dept. of Electrical Engineering, NIT Patna**

   Coordinator: Dr. Amitesh Kumar

2. FDP course **"Renewable Energy: Research to Industry " (22nd-Aug. 13th Sep. 2020) was organized at Dept. of Electrical Engineering, NIT Patna**

   Coordinator: Dr. Amitesh Kumar

3 FDP course **"Electrical Vehicles and Mobility " from 24-01-2022 to 04-02-2022 was jointly organized by NIT Patna, MNIT Jaipur, IIIT Jabalpur**

   Coordinator: Dr. Amitesh Kumar (NIT Patna)

4 FDP course **Next-generation Applications in Electrical and Electronics Engineering" from 15th September to 20th September "** from **24-01-2022 to 04-02-2022 was organized at Dept of Electrical Engineering, NIT Patna**

   Coordinator: Dr. Amitesh Kumar (NIT Patna)

5. FDP course **"Blockchain Technology for Next-Generation Applications"** from **19th June 24th June 2023 was organized at Dept of Electrical Engineering, NIT Patna**

   Coordinator: Dr. Amitesh Kumar (NIT Patna)

6 FDP course **"Research Methodology For Social Sciences, Engineering and Management: NEP 2020 (RMSSEM 2023)"** from **10th July- 14th July 2023 was organized NIT Patna**

   Coordinator: Dr. Amitesh Kumar (NIT Patna)

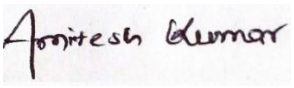
Ongoing Project

1. **Project Title : Bio-Inspired Synaptic Cells for Neuromorphic and Biomedical Applications**
   Project File No: SRG/2021/002110
   Funding Agency: Department of Science & Technology
   Amount of Project: 2900000.00

Collaborative work with different groups

1. **Hybrid Nanoelectronics Research Group** **Experimental fabrication (Ph.D. Lab)**

2.	**RMIT, Australia**	**Micro/nano fabrication facility**
3.	**Shinshu University, Japan.**	**HR-TEM**
4.	**Low Power Nanoelectronics Research Group, IIT, Indore**	**Modelling and simulation (Ph.D. Lab)**
5.	**Supramolecular Chemical Nanoscience Group, IIT Indore**	**Organic material synthesis**
6.	**RRCAT, Indore**	**Beamline facility**
7.	**SNU, Noida**	**AFM facility**

Place: **NIT Patna, India** **Signature** 

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OBJECTIVE

Seeking a challenging role that requires knowledge, skills, and experience in the following areas:

1. Biological safety evaluation associated with medical devices and component materials, and process changes in accordance with ISO 10993 and other national and international standards.
2. Toxicological risk assessment on extractable and leachable profile of the medical devices.
3. Biocompatibility testing strategy for new products and sustaining products that include studies using in vitro culture and in vivo animal models.
4. Compliance with internal standards and regulatory requirements to ensure the efficacy and safety of medical devices.

PROFESSIONAL SUMMARY

Biocompatibility and Toxicology Specialist with 13+ years of experience in biological safety evaluation and toxicological risk assessment of medical devices as per ISO 10993 standards. Proven history as a successful biocompatibility scientist from a combination of industry experience working in the medical device industry for new product development and life cycle management of sustaining products and hands-on experience working in a CRO as a study director for different classes of medical devices. Having an in-depth technical knowledge of the ISO 10993 standards and regulatory requirements in the US and EU. Expert in developing biocompatibility testing strategy, biological evaluation plan, executing the biocompatibility testing, and authoring biological evaluation report for successful regulatory submissions. Member of BIS ISO 10993 committee, India. Having an excellent record as an international speaker/trainer in ISO 10993 standards to leading manufacturers and regulatory bodies like Saudi FDA (SFDA), HOYA Optics-Thailand, and LG Chem-Korea and as a speaker in national conferences like “Medical Device Regulatory and Quality Summit”, in 2017 and 2022, India and organized multiple 10993 Biocompatibility workshops in India.

PROFESSIONAL EXPERIENCE

Organization	Designation	Duration
Baxter Healthcare	Research Scientist II	Dec 2023-Present
Baxter Healthcare	Research Scientist I	Aug 2018-Nov 2023
UL India Private Limited	Biocompatibility Engineer	May 2017-Jul 2018
GLR Laboratories Pvt Ltd	Senior Scientist	May 2010-Apr 2017

EDUCATION

Advanced Comprehensive Course in Toxicology, American College of Toxicology, 2020
Master of Science (Biotechnology) - Vinayaka Mission University, India, 2013
Bachelor of Technology (Biotechnology), Anna University, India, 2008

RESPONSIBILITIES

Current Employer: Baxter Innovations and Business Solutions Private Limited

Position: Research Scientist - Biocompatibility Lead, Infusion Therapies and Technologies, Medical Products & Therapies

1. Perform gap analysis and execute biocompatibility testing to remediate the gaps to meet the state-of-the-art requirements.
2. Perform biocompatibility/toxicology impact assessments for the process changes in the existing products based on the biological risk management process.
3. Collaborate with cross-functional team members (engineering, extractable and leachable, materials, sterility, etc.) to determine a comprehensive testing strategy.
4. Monitoring biocompatibility studies in external CROs, technical review of study protocols, and test reports.
5. Authoring BEP and BER for regulatory submissions.
6. Effectively coach and mentor junior team members.
7. Develop biocompatibility testing strategies to qualify new products and materials per global standards. Ensure compliance with regulatory guidelines such as ISO, ASTM, and USP 87 and 88.
8. Develop preclinical regulatory summaries for DHF files, USA FDA 510 K submissions, and CE Mark.

9. Utilize Siemens Team Center Unified global material management system (GMMS) for biocompatibility testing, product development, and registration support.
10. Develop project schedules; provide estimates and timelines to meet project milestones.
11. Attend Project Review and Core team meetings.
12. Implement the use of ISO10993-1, regional pharmacopeia, 21 CFR Part 58 Good Laboratory Practices for Non-Clinical Laboratory Studies, and/or other regulatory guidance documents to qualify Baxter products.
13. Performing toxicology risk assessment of extractable and leachable in line with ISO 10993-17.

Previous Employer: Underwriters Laboratories Private Limited, Bangalore, India

Position: Biocompatibility Engineer

1. Conduct international and national biocompatibility training, workshops, seminars, and webinars.
2. Design and recommend testing strategies to global customers.
3. Biological safety assessment of medical devices to issue "Declaration of Compliance" (DoC) to ISO 10993.
4. Genotoxicology assessment of leachable from medical devices using the TTC concept based on ICH M7 guidelines.
5. Recommend toxicology testing requirements for medical devices as per ISO 10993 standards.
6. Design study protocol for toxicology testing as per regulatory needs.
7. Monitor toxicology studies and review reports.
8. Recommend toxicology testing requirements of medical device packaging materials as per ASTM standards.
9. Recommend toxicology testing requirements of raw materials like plastics and elastomers as per USP 87 and 88.
10. Conduct a literature search to support toxicology risk assessment of implant devices.
11. Perform toxicology risk assessment of medical devices, pharmaceutical containers, bioreactors, etc., based on extractable and leachable testing.
12. Establishment of allowable limits of leachable substances from medical devices based on ISO 10993-Part 17.
13. Design chemical characterization test methods for medical devices in consultation with a chemist and material scientist followed by a risk assessment of toxicology.
14. Risk management of medical devices as per ISO 14971.

Previous Employer: GLR Laboratories Pvt Ltd, India

Position: Senior Scientist

1. To scientifically conduct the non-clinical toxicity studies in compliance with the Principles of GLP, regulatory guidelines and animal welfare guidelines.
2. To plan, conduct and monitor the studies required to be conducted in the toxicology department.
3. To take part and monitor the study related activities like study designing, study plan writing, experimental procedures, data recording and analysis, report writing and archiving.
4. To prepare and review SOPs required for day to day working in the areas of direct concern and to review and provide inputs in the SOPs of the other related groups.
5. To conduct, participate, supervise, and ensure the validation studies are conducted wherever/whenever required in the group.
6. To ensure, in case of multisite studies, as Study Director, that the delegated Phase of the study is being performed in compliance with the Principles of GLP.

Study Director

1. Conducted more than 300 biocompatibility studies in a GLP Set up as a Study director.
2. Supported different class of devices like implants, catheters, disposables, dialyzers, stents, IOLS, respiratory and cardiovascular devices.
3. Hands on experience in cytotoxicity, irritation, sensitization, acute/sub chronic systemic toxicity, implantation, genotoxicity, hemocompatibility and pyrogen testing of medical devices.
4. To act as the single point of study control and take the responsibility for the overall conduct of the study and for its final report.
5. To approve the study plan and any amendments to the study plan by dated signatures.
6. To ensure that the Quality Assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the Quality Assurance personnel as required during the conduct of the study.
7. To ensure that study plans and amendments and Standard Operating Procedures are available to study personnel.
8. To ensure that the study plan and the final report for a multi-site study identify and define the role of any Principal Investigator(s) and any test facilities and test sites involved in the conduct of the study.
9. To ensure that the procedures specified in the study plan are followed and assess and document the impact of any deviations from the study plan on the quality and integrity of the study and take appropriate corrective action if necessary; acknowledge deviations from Standard Operating Procedures during the conduct of the study.

10. To ensure that all raw data generated is fully documented and recorded.
11. To sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with the Principles of Good Laboratory Practice.
12. To ensure that after the study's completion (including termination), the study plan, the final report, raw data, and supporting material are archived.

CERTIFICATIONS, CONFERENCES, AND TRAINING

1. Conference Speaker "Regulatory Compliance in Biocompatibility Testing" - Medical Device Evolution: Advancements and Innovations Webinar, 5 Sep 2024, Virtual.
2. Attended 42nd Annual Conference of the Society of Toxicology, India (STOX 2023), Calicut, Kerela, Nov 23-25, 2023.
3. Attended EUROTOX 2023 Conference - 57th Congress of the European Societies of Toxicology, Ljubljana, Slovenia. 10th -13th Sep 2023.
4. Conference Speaker- "Current Challenges in Biocompatibility Testing of Medical Devices"-6th Annual Medical Device Regulatory and Quality Summit, 2022, India
5. Course-Certificate of completion in "Dose-Response Assessment Boot Camp" by TERA-Toxicology Excellence for Risk Assessment, 2022, India
6. Conference Participant-MedTech Summit Virtual Event - Biocompatibility of Medical Devices, 2020, Virtual event, UK.
7. Course-Advanced Comprehensive Virtual Course in Toxicology, American College of Toxicology, 2020
8. International training - Biocompatibility testing requirements for medical devices, HOYA Optics-Thailand, 2019
9. Conference Participant-Asian Federation of Laboratory Animal Science (AFLAS) Conference, 2018, Bangalore, India.
10. Training-Quality Management System Training: ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories, 2018, UL India.
11. Speaker-National Workshop- "Biological safety evaluation of medical devices", 2018, New Delhi, India.
12. Speaker-National Workshop- "Biological safety evaluation of medical devices", 2018, Ahmedabad, India.
13. Course-Certificate of completion in "Train the Trainer" course, 2017, India
14. Conference Speaker-Strategy for biocompatibility evaluation of medical devices, 2nd Annual Medical Device Regulatory and Quality Summit, 2017, India
15. International training - "Overview about 10993 standards and requirements" to Saudi FDA (SFDA), 2017, Saudi Arabia.

16. International training - Implementation of Biocompatibility requirements based on ISO 10993, LG Chem - UL joint seminar, 2017, South Korea

PUBLICATION

B.Brabu, S.Haribabu, M.Revathy, S.Anitha, M.Thangapandiyan, K.R.Navanethakrishnan, C.Gopalakrishnan, S.S.Murugan, T.S.Kumaravel. Biocompatibility studies on lanthanum oxide nanoparticles. Toxicology Research. 2015; 15, 43-30.

Annexure B

Composition of Ophthalmic Instruments and Appliances Sectional Committee, (MHD 05)

S. No.	Organization	Member Name	Role	17th meeting 13/05/2024	18th meeting 02/09/2024	Attendance (2/2)
1.	University College of Medical Sciences, New Delhi	Jolly Rohatgi	**Chairperson**	P	P	2/2
2.	Akriti Ophthalmic Private Limited, Hyderabad	Kuldeep Raizada	Principal Member	P	P	2/2
3.	Appasamy Associates, Chennai	K.Rengasamy	Principal Member	A	A	0/2
		R.Vijay	Alternate Member	A	A	1/2
		Rajesh Candamourty	Alternate Member	P	P	2/2
4.	Aravind Eye Hospital, Madurai, Tamil Nadu, India	Shivakumar. C	Alternate Member	P	P	2/2
		Karthik Srinivasan	Principal Member	A	A	0/2
5.	Auro Lab, Madurai	R. Krishna Kumar	Principal Member	P	P	2/2
		R. Sundaraganesh	Alternate Member	P	A	2/2
		Ramnath	Alternate Member	A	A	0/2
6.	CSIR - National Physical Laboratory, New Delhi	V. K. Jaiswal	Principal Member	P	P	2/2
		Parag Sharma	Alternate Member	A	A	0/2
7.	Carl Zeiss India (Bangalore) India Private Limited, Bangalore	Dattatraya Hegde	Principal Member	P	P	2/2
8.	Central Drugs Standard Control Organization, New Delhi	Aseem Sahu	Principal Member	P	P	2/2
		Shyamni Sasidharan	Alternate Member	P	P	2/2
		Gulhane Akshay Dinkar	Alternate Member	P	P	2/2
9.	Dr Rajendra Prasad Centre for	J.S. Titiyal	Principal Member	P	P	2/2
		Praful. K. Maharana	Alternate Member	P	A	1/2

	Ophthalmic Sciences, New Delhi					
10.	Iscon Surgicals Limited, Jodhpur	Narendra Kumar Jain	Principal Member	P	P	2/2
		Vishrut Jain	Alternate Member	A	A	0/2
		Deepak Singhvi	Alternate Member	A	A	0/2
11.	Kalam Institute of Health Technology, Vishakhapatnam	Arpita	Principal Member	P	A	1/2
		Kanhu Lenka	Alternate Member	P	P	2/2
		Divya Anil Patil	Alternate Member	P	A	1/2
12.	L V Prasad Eye Institute, Hyderabad	Rathinam Thyagarajan	Principal Member	P	P	2/2
		PremNandhini Satgunam	Alternate Member	P	P	2/2
		Nabeel Quadri	Alternate Member	P	P	2/2
		Sandeep Reddy Padamati	Alternate Member	A	A	0/2
13.	Lady Hardinge Medical College, New Delhi	Sarita Beri	Principal Member	P	A	1/2
		Piyush Kumar	Alternate Member	A	A	0/2
14.	Sankara Nethralaya, Chennai	Prof. Rajiv Raman	Principal Member	A	P	2/2
		Chetan Rao	Alternate Member	A	A	1/2
		Nisar Sonam Poonam	Alternate Member	A	A	1/2
15.	In Personal Capacity	Balachandar Settu	Personal Capacity	P	P	2/2
16.	In Personal Capacity	Shankar Balasubramanian	Personal Capacity	New	P	1/2

Ophthalmic Scan A and B

1. Scope:

This Indian Standard specifies general requirement functional, safety requirements and test methods for Ophthalmic Scan A and B used for ultrasound examinations performed for eye evaluation.

2. **References**:

The standards listed below contain provisions which, through reference in this text, constitute provision of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards

IS No./Other Publication	*Title*
IS 13450 Part 1 Sec 2:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
ISO 22665:2012	ISO 22665:2012, Ultrasonics — Pulse-echo scanners — Simple methods for periodic testing to verify stability of an imaging system's elementary performance.
IS 13450 (Part 2/Sec 37):2019/IEC 60601-2-37	Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
IS 13450 (Part 2/Sec 22):2021/IEC 60601-2-22	Medical electrical equipment - Part 2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IS 18638 (Part 1) :2024	Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments.
ISO 15004-2:2007	Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection.

3. Terms and Definitions

3.1 Axial length: distance along the axis of a human eye between the anterior corneal surface to either the inner limiting membrane (ILM) of the retina or the retinal pigment epithelium (RPE) of the retina.

3.2 A-Scan :A form of ultrasonography used to measure the length of the eye and other axial distances within the eye. It provides a one-dimensional representation of the reflected ultrasound waves, showing the amplitude of the echoes as a function of time or distance.

3.3 B-Scan: A form of ultrasonography that provides a two-dimensional cross-sectional image of the eye and the orbit. It shows the intensity of the reflected ultrasound waves as a brightness modulation on the display, representing various tissues and structures within the eye and the orbit

3.4 Aphakic mode
measurement mode and/or instrument setting for an axial length measuring device which is to be used for the measurement of an aphakic eye (eye without lens)

3.5 Contact ultrasound
contact mode
coupling technique in A scan biometry by which the measuring transducer probe is in direct contact with the cornea

3.6 Time Delay Method
This method involves sending an ultrasonic pulse into the eye and measuring the time it takes for the echoes to return from various structures.

3.7 Immersion ultrasound
Immersion mode coupling technique in A scan biometry by which the measuring transducer probe is separated from the cornea by a water or liquid standoff

3.8 Phakic mode
measurement mode and/or instrument setting for an axial length measuring device which is to be used for the measurement of a phakic eye (eye with a crystalline lens)

3.9 Acoustical impedance Z
material property defined as the product of the velocity of sound in that material with its density: $Z = \upsilon \times \rho$ where υ is the velocity of sound in the material and ρ is the density of the material.

3.10 Spike: It is a representation a reflection from a specific interface or structure within the eye Refer to clause number 3.1.6, 3.1.7, 3.1.8 from ISO 15004-2.

4. Requirements

4.1 General Requirements

4.1.1 The device shall be of robust construction, operable by semi-skilled users.

4.1.2 The minimum resolution of the image shall be 640 x 480 pixels.

4.1.3 There must be a processing unit for signal processing, data storage and analysis of the results.

4.1.4 The device shall have provision for sharing the captured images through internet to health care provider through suitable transmission mode and in different formats.

4.1.5 There shall be provision for storage of minimum 1,000 captured images.

4.1.6 The device must be portable for the doctors to move from one place to another.

4.1.7 The Probe zero calibration is needed for maintaining precise measurements and images.

4.1.8 There must be a processing unit for signal processing, data storage, analysis of the results and changing modes.

4.1.9 The general requirements of this standard also include the clause 4 - Fundamental requirements i.e.,4.1 general, 4.2 Design, 4.3 Performance, 4.4 Combination of different devices, 4.5 Materials 4.5.1 For contact method of Ophthalmic A scan and B scan, 4.6 Protection againt Contaminants, 4.7 Scales and Displays of the ISO 15004-1:2006

4.1.10 Refer Clause 4-stating Annex A -A.1(Test bodies and Evaluation of measurements) excluding Table 4.1(optical biometry)

4.2 Functional Requirements

The essential parts of the device shall meet the following requirements:

4.2.1 The device shall have a robust touchscreen to facilitate navigation through the software application for screening and image capturing.

4.2.2 The device shall have Bluetooth or other interface capability to connect to accessories, such as a Bluetooth printer to print patient receipts.

4.2.3 The device shall comply with the general and electromagnetic compatibility requirements of IS 13450 (part 1) / IEC 60601-1 and IS 13450 (part 1 / Sec 2)/ IEC 60601-1-2.

4.2.4 The device shall comply to requirements of medical electrical equipment IEC 60601-1 clause 4-General requirements, clause 7-Protection against electrical hazards, clause 9-

Mechanical Hazards ,clause 10- Protection against Unwanted and Excessive Radiation of the IEC-60601-1 Standard

4.2.6 The axial length and corneal curvature measurements should be accurate and precise and results must not vary much i.e., standard deviation must be less than 1.

4.2.7 The dimensions of the probe must be that it is handy, light weight and durable to use. Refer clause 15- Constructional requirements- sub clause 15.3- Enclosures and Protective covers ensuring the construction of the device is capable and durable.

4.2.8 The Scan method can be Contact or Immersion depending on the patient's condition i.e., for a post operative patient contact method must be avoided to eliminate the factor of discomfort.

4.2.9 The Gain should be set in such a way that it offers a wide dynamic range range to adjust contrast and visibility of the images produced by the system.

4.2.10 The frequency of probe must be optimal i.e. 8-12Mhz for A-scan for optimal spatial resolution and depth of penetration and 10-20Mhz for B scan providing high resolution, fine details and proper brightness in the images.

4.3 Safety requirements

Ophthalmic A scan and B scan should also comply with **clause 5**(requirements) excluding point number (c) of the **5.2** subclause, 5.4.1(continuous wave instruments), 5.5.1 (Emission limits and guideline values for Group 2 instruments- continuous wave instruments of standard ISO 15004-2:2007. 5.4.3 and 5.5.3(Emission limits and guideline values for Group 1 instruments- multiple source instruments & Emission limits and guideline values for Group 2 instruments- multiple source instruments respectively).

It should also cover sub-clause 4.8 Thermal Hazards, 4.9 Mechanical Hazards and clause 6 of the IS 18638 (Part 1)

5. Tests/ Test Methods

5.1 General Tests

The manufacturer must follow the clause 7- Test methods and sub clauses 7.1 General, 7.2 Ignitability, 7.3 Surface temperatures, 7.4 Electrical Safety of the IS 18638 (Part 1)

5.2 Testing the parameters and Measurements of the test bodies

The test methods of this standard must comply with the clause 5 - Test methods and excluding subclause 5.4 Measurements with optical biometry instruments of the standard IS 18586.

5.3 Probe Frequency Test

For A scan:

Expose the test bodies with different Frequencies e.g. (10 MHz) and check the axial length by time delay method or amplitude of the reflected waves i.e, echoes and match the results when tested with human eye's axial length (between the corneal apex to the retinal pigment epithelium).

For B scan:

Expose the test bodies with frequencies from 10Mhz to 20 Mhz according to the depth of imaging required and place the probe perpendicularly on the test body to minimize movement.

Acquire the ultrasound images using the B scan mode and adjust the depth and gain settings accordingly.

Verify the image quality by looking for details like the clarity of tissue layers or any developments in the eye and compare all reports generated using different frequencies.

Note: The human eye has an axial length of 22-24 mm so the depth settings must be adjusted accordingly.

5.4 Accuracy Test

Use contact or immersion method and perform multiple measurements on the test body if the results are consistent and the standard deviation comes out to <1. The probe's measurements are accurate.

6. Marking

Each ophthalmic scan A and B machine shall be marked with the following:

a) Manufacturer's name/ trademark,

b) Name and address of the manufacturer,

c) Name and address of the marketer,

d) Month and Year of manufacture,

e) Unique Device Identification / serial number

8. BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the Bureau of Indian Standards Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

9. Packing

The device and its accessories shall be packed in a case in such a way that they are intact in the case. 9.1 The box or the case for the device shall be made of a suitable material. It shall be so designed that when the device and accessories are kept in position and the lid is closed, there shall be no rattling inside the case.

Annexure D

CDSCO LIST

S.N.	Device Name	Intended Use	Risk Class	Relevant Standard
1.	Adaptometer	An ophthalmic device intended to measure the time required for retinal adaptation and The minimum light threshold.	B	
2.	Amsler grid	An ophthalmic device intended to rapidly detect central and paracentral irregularities in the visual field.	A	
3.	Anomaloscope	An ophthalmic instrument used to test a patient for abnormal red/green colour vision by differentiating the red/green colour vision defects.	A	ISO/DIS 5868
4.	Aqueous/vitreous humour replacement medium kit	A collection of sterile devices, including a fluid or semifluid substance, used in combination to replace the fluid of the eye.	D	IEC 80601-2-58:2014/ Amd 1:2016
5.	Automated lensmeter (Dioptometer)	An ophthalmic instrument designed to measure the focusing power (dioptric power) and other Optical characteristics of a spectacle lens, contact lens, or prism.	A	IS/ISO 8598-1 : 2014
6.	Bagolini lens	An ophthalmic plane lens, intended to determine harmonious/anomalous retinal Correspondence.	A	
7.	Binocular vision test unit	An ophthalmic device for binocular vision testing.	A	
8.	Blepharoplasty scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut eyelid tissue during plastic surgery of the eyelids (Blepharoplasty).	A	
9.	Capsular bag anchor	A device intended to be permanently implanted in the posterior chamber of the eye for correction and fixation of a subluxated Capsular bag, typically in association with in- the-bag intraocular lens (IOL) implantation.	C	
10.	Colour discrimination tester	An ophthalmic lamp, used to test a person's ability to differentiate between colours.	A	
11.	Colour-discrimination eye	Intended for testing colour vision.	A	

	chart			
12.	Conjunctival scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut the Conjunctiva and Tenon's capsule on the eye surface to access the sclera.	A	IS 4569 (Part 2) : 1985
13.	Contact Lens (Including Coloured Contact Lens)	Device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a Therapeutic bandage or/and to change the appearance of the eye for decorative purposes.	B	IS/ISO 18369
14.	Contact lens agitation cleaning system	An assembly of devices used to clean and Disinfect contact lenses through automated or manual mechanical agitation.	B	
15.	Contact lens disinfecting solution	An aqueous formulation containing Appropriate agents for loosening debris from contact lenses, and that contains a disinfectant intended to act on contact lens.	B	
16.	Contact lens protein-removal solution	A formulation of proteolytic enzymes, used to remove debris and protein deposits from Reusable contact lenses, or to remove protein deposits only.	B	
17.	Contact lens radius gauge	A measuring instrument used in ophthalmology to determine the radius of curvature of contact lenses.	A	ISO 10343:2014)
18.	Contact lens thermal cleaner	A unit intended to disinfect or sterilize reusable soft contact lenses by means of heat.	B	
19.	Corneal burr manual instrument	A hand-held, ophthalmic surgical instrument, used to excavate corneal tissue through manual rotation.	B	
20.	Corneal burr system	An assembly of devices designed for abrasion of the cornea and other eye tissues.	B	
21.	Corneal burr, abrasion	A device designed for abrasion of the cornea to polish corneal scratches and/or the pterygium bed after surgical removal, and/or for abrasion of lid margin lesions.	B	
22.	Corneal burr, rust ring removal	A device designed for gentle removal of rust stains (rust rings) from the cornea after the extraction of a ferrous foreign object.	B	
23.	Corneal epithelium perforator	Intended to create a number of small perforations in the epithelial layer of the cornea through which riboflavin can pass into the cornea during corneal collagen crosslinking, to treat corneal ectasia (typically keratoconus).	B	
24.	Corneal epithelium trephine	Intended to create a circular cut through the epithelial layer of the cornea to create an epithelial flap intended to be folded back during laser assisted epithelial keratomileusis	B	

		(LASEK) surgery, after which the flap is replaced.		
25.	Corneal inlay, aperture reducing	An implantable device inserted into the natural cornea to treat presbyopia based on aperture reduction.	C	
26.	Corneal inlay, cornea-reshaping	An implantable device inserted into the natural cornea to treat refractive errors by reshaping the cornea.	C	
27.	Corneal light shield	A device typically made of a nonabrasive fluid-absorbing material that is placed on the surface of the cornea to shield the retina from excessive illumination during an ophthalmic procedure.	B	
28.	Corneal marker	A manual instrument intended to be used to imprint, indent, and/or incise corneal tissue prior to an ophthalmic surgical procedure.	B	
29.	Corneal resection holder	A device designed to hold donated corneal tissue so that it can be resected in preparation for transplantation.	B	
30.	Corneal scissors	A hand-held, manual, ophthalmic surgical Instrument intended to be used to cut corneal tissue.	B	IS 4569 (Part 1) : 1985
31.	Corneal shield	A mechanical eye shield made of collagen that is placed on the eye to protect the Cornea.	B	
32.	Corneoscleral punch	A hand-held, manual ophthalmic surgical instrument designed to excise a segment of Tissue from the sclera or cornea of a patient or from grafts taken from cadaver donors.	B	
33.	Diagnostic condensing lens	An ophthalmic lens used in binocular indirect ophthalmoscopy to focus reflected light from the fundus of the eye.	A	
34.	Donor cornea container	A receptacle intended to maintain, transport, and facilitate clinical examination of a Donated cornea during the period between cornea collection and transplantation surgery.	C	Taken up for the standard formulation
35.	Eikonometer	An ophthalmic instrument for diagnosing aniseikonia.	A	
36.	Electronic occlusion spectacles	An ophthalmic device designed to test and train vision for conditions where decreased Visual acuity may be due to unequal vision in the eyes.	A	
37.	Endoscopic-imaging ophthalmic solid-state laser system	A device assembly intended to treat retinal and other eye disorders, such as glaucoma, during endoscopic cyclophoto coagulation (ECP) procedures.	C	

38.	Enucleation scissors	A hand-held, manual, ophthalmic surgical instrument used to cut tissue during eye surgery involving enucleation of the eye and/or its related structures.	A	IS 4569 (Part 4) : 1985
39.	Epiretinal/inner limiting membrane scraper	A hand-held manual surgical instrument intended to be used during posterior segment surgery to lift the inner limiting membrane (ILM) and/or an epiretinal membrane (ERM), and which may have additional posterior segment membrane manipulation uses.	B	
40.	Euthyscope	A modified ophthalmoscope that projects a bright light encompassing an arc of approximately 30 degrees on the fundus of the eye for the Treatment of amblyopia.	A	
41.	Exophthalmometer	An ophthalmic instrument used to measure the degree of exophthalmos.	A	
42.	Eye cup	A receptacle designed to fit around the eye socket and which is filled with warm water or an eyewash solution and placed over the eye to allow the liquid to wash the affected Eye.	A	
43.	Eye heat therapy pack	A device intended to be placed over closed eyes to apply heat for the treatment of meibomian gland dysfunction (MGD), dry eye syndromes, blepharitis and other related ocular conditions.	B	
44.	Eye irrigation shield	A device intended to be used with an eye irrigation kit/system to direct irrigation solution to the surface of the eye and allow the solution to gently lavage the surface of the eye.	A	
45.	Eye muscle clamp	An hand-held manual ophthalmic surgical instrument designed to a traumatically grasp and hold the extraocular muscles (EOM) during an ophthalmic surgical intervention.	B	IS 9688 : 1992
46.	Eye muscle sleeve	An implantable device made from synthetic materials that is used to encase or isolate an ocular muscle.	C	
47.	Eye pad	A sterile, cushion-like device intended to protect the eye or to absorb eye secretions.	A	IS 17628 : 2021
48.	Eye spud	A hand-held, manual, ophthalmic surgical instrument intended to be used to remove a Foreign body/object embedded in or adhering to the surface of the eye globe.	A	
49.	Eye valve	An implantable device designed to regulate the flow of fluid between the anterior chamber and the space Around the conjunctiva of the eye by allowing flow when the pressure in the chamber is above a pre-set value.	C	

50.	Eyelid clamp	A hand-held manual surgical Instrument designed to a traumatically grasp and hold the eyelid during an ophthalmic surgical intervention.	A	IS 7762 : 1975
51.	Eyelid weight, external	An ophthalmic device that is applied to the outside of the upper eyelid to "lid load" the Eyelid to restore upper eyelid muscle function.	A	
52.	Eyelid weight, implantable	An ophthalmic device that is implanted subcutaneously within the upper eyelid to "Lid load" the eyelid to restore upper eyelid muscle function.	C	
53.	Felt tangent screen	A black tangent screen intended for assessing the extent of the patient's peripheral Visual field by mapping the visual response to a test object moved from the periphery towards the center of the screen.	A	
54.	Femtosecond ophthalmic solid-state laser system	A device assembly in which input energy is used to excite a glass/crystal rod to emit a High-power laser beam intended for ocular resections and incisions.	C	
55.	Fibreoptic general-purpose ophthalmic hook	A hand-held manual surgical instrument inserted into the eye during surgical intervention to manipulate anatomical structures or foreign Bodies within the eye and simultaneously conduct a field of cold light to illuminate the surgical site.	A	
56.	Flieringa ophthalmic ring	A circular band, sutured to the sclera to prevent collapse of the globe during difficult intraocular operations.	A	
57.	Fornix scope	A manually-operated, ophthalmic device intended to provide indirect access and viewing of the upper conjunctival fornix and inner surface of the eyelid as an alternative to eyelid eversion.	A	
58.	Fresnel lens	A very thin and flexible ophthalmic lens intended to be applied to the back of spectacle lenses to focus light to a focalpoint to help manage various vision conditions.	A	
59.	Fresnel prism	A device intended to be applied to spectacle lenses to give a prismatic effect typically to manage strabismus or other eye muscle dysfunction.	A	
60.	Fundus-imaging ophthalmic diode laser system	Intended for: ocular laser treatment procedures, including coagulation of abnormal retinal vasculature; and capturing real-time digital images of the anterior/posterior eye segments created using colour, fluorescein angiography and infrared	C	IS/ISO 10940 : 2009

		imaging, for Diagnosis/treatment planning.		
61.	Fundus imaging ophthalmic solid-state laser system	Intended to coagulate abnormal vascular tissue in the retina and for other ocular photocoagulation procedures.	C	
62.	Glaucom supraciliary implant	A non-bio absorbable synthetic polymer device designed to be implanted in the supraciliary space (between the ciliary muscle/body and the sclera) for the restoration of aqueous humour outflow and subsequent reduction of intraocular pressure as part of Treatment for open angle glaucoma.	C	
63.	Glaucoma therapy ultrasoun d system	A system designed to transduce radio-frequency (RF) electrical energy from a generator into ultrasound energy, for the extracorporeal application of high intensity focused ultrasound (HIFU) to the eye, to decrease aqueous humour production and reduce intraocular pressure (IOP)	C	
64.	Haidinger brush imager	An ophthalmic device designed to produce an image which facilitates his/her visual Function evaluation, particularly the macular integrity.	A	
65.	Hand-held campimeter	A portable, hand-held device intended for assessing the central 30º visual field.	A	
66.	Hand-held telescope	A device that consists of an arrangement of ophthalmic lenses or mirrors with a handle Intended to enlarge images for a visually impaired patient/person.	A	
67.	Hand-held telescope	A device that consists of an arrangement of ophthalmic lenses or mirrors with a handle Intended to enlarge images for a visually impaired patient/person.	A	
68.	Hruby fundus lens	A 55 diopter non-contact diagnostic ophthalmic lens intended for use in the Examination of the vitreous body and the fundus of the eye under slit lamp illumination and magnification.	A	
69.	Implantable intraocular pressure monitoring system	An assembly of portable devices intended to continuously or regularly collect and display intraocular pressure (IOP) data for the diagnosis/monitoring of glaucoma.	C	
70.	Implantable iris prosthesis	An optical device intended to be implanted into the posterior chamber of the eye for the Reconstruction of partial or total iris defects.	C	
71.	Indirect binocular	An ophthalmic instrument designed to examine the interior of the eye allowing the	A	IS/ISO 10943 :

	ophthalm os ope	examiner to clearly see a wide angle, stereoscopic impression of the details of the fundus (retina) and other structures.		2011
72.	Intracorneal ring	An implantable, open-ended circular band designed to flatten the anterior corneal curvature, without disturbing the visual axis, to correct mild and Moderate myopia.	C	
73.	Intranasal lacrimal neurostim ulator	A hand-held device intended to be seed in the home to provide electrical stimulation to sensory neurons of the nasal cavities to acutely increase tear production as treatment for aqueous deficient dry eye.	C	
74.	Intraocular pressure-reducing system	An assembly of manually operated devices designed to reduce the intraocular pressure (IOP) by applying a controlled, external, mechanical compression to the surface of the eye in preparation for ophthalmic surgery.	C	
75.	Keratome	An ophthalmic surgical instrument intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.	B	IS 8163 : 1976
76.	Lacrimal tube	A implantable, single-lumen tube intended to provide tear drainage from the front Surface of the eye, and also to facilitate saline solution irrigation to a paranasal sinus to manage chronic rhino sinusitis.	C	
77.	Lens spoon	A hand-held ophthalmic surgical instrument used in ophthalmic surgery to manipulate/remove the lens of the eye.	A	
78.	Maddox trial lens	A special ophthalmic trial lens in the form of a rod or series of rods (grooves/cylinders) that changes the size, shape, and colour of an image to dissociate the eyes in the Evaluation of eye muscle dysfunction.	A	
79.	Mirror-prism spectacles	An optical device intended to enable the patient to see over the top of their head Enabling them to look forward in the direction their head is pointing.	A	
80.	Nystagmus inducing optokinetic drum	An ophthalmic device intended to elicit nystagmus.	A	
81.	Nystagmus inducing tape	An ophthalmic device intended to be moved across a patient's field of vision to elicit Optokinetic nystagmus and to test for blindness.	A	
82.	Ophthalmic calliper	A hand-held manual ophthalmic measuring instrument consisting of two legs hinged at one end and designed to measure the diameter, length, angles, and thicknesses of the eye.	A	IS 9626 : 2023

83.	Ophthalmic clip	A device typically made of a malleable metal (e.g., tantalum), intended to be implanted permanently or temporarily to bring together the edges of a wound, to aid in healing or to prevent bleeding from small blood vessels in the eye.	C	
84.	Ophthalmic cryosurgical system	An assembly of devices designed to apply cold from a gaseous or liquid refrigerant (cryogen) to a target tissue for its destruction and removal during an ophthalmic surgical procedure.	C	
85.	Ophthalmic distometer	An ophthalmic instrument designed to measure the distance between the cornea and a Spectacle or trial lens (vertex distance).	A	
86.	Ophthalmic dye laser system	A laser device assembly intended to coagulate abnormal vascular tissue in the retina, and for other photocoagulation procedures in the eye.	C	
87.	Ophthalmic excimer laser system	A laser device assembly intended for corneal ablation and other ophthalmologic procedures.	C	
88.	Ophthalmic head reflector	A head-worn ophthalmic device intended to reflect light onto the eye of a patient to allow examination of the eye and its associated structures.	A	
89.	Ophthalmic Irrigation Solution (Balanced Salt Solution)	Intended for the irrigation of the anterior chamber during cataract surgery and other intraocular or extraocular procedures or for the irrigation of the conjunctiva following application of fluorescein or for moistening the corneal and Conjunctival surface during laser treatment.	B	IS/ISO 16671 : 2015
90.	Ophthalmic noble gas laser system	A laser device assembly intended to coagulate abnormal vascular tissue in the retina and for other photocoagulation procedures in the eye.	C	
91.	Ophthalmic operating table top	A component of a modular operating table intended to provide support for and stabilization of the head of the patient (typically includes a headrest) and to help provide optimal access for the surgeon(s) during the intervention (e.g., by having a	A	
92.		small-width table top and therefore a shorter stretch Distance for the surgeon).		
93.	Ophthalmic soft-tissue surgical forceps	A hand-held manual instrument designed to grasp and manipulate intraocular tissues during ophthalmic surgery (e.g., anterior segment surgery, vitreo-retinal procedures, iridectomy, capsulorhexis).	B	IS 5668 : 1989

94.	Ophthalmic surgical device handling forceps	A hand-held manual surgical instrument with blades designed to grasp and manipulate a no implantable invasive ophthalmic surgical device (e.g., ophthalmic cannula, handless iris retractor) and/or for ophthalmic suturing.	A	
95.	Ophthalmic suture scissors	A hand-held, manual, ophthalmic surgical instrument intended to be used to cut suture during eye surgery.	A	
96.	Ophthalmic tonometer	An ophthalmic, measuring instrument designed for determining the intraocular pressure (IOP).	B	IS/ISO 8612 : 2009
97.	Ophthalmic ultrasound imaging system	An assembly of devices designed for ophthalmic ultrasound imaging procedures.	B	
98.	Ophthalmodiastimeter	An ophthalmic instrument for determining the proper distance at which to place Prescription lenses for the two eyes.	A	
99.	Ophthalmoleukoscope	An ophthalmic device intended to be used for testing colour perception by means of colours produced by polarized light.	A	
100.	Ophthalmoscope	An ophthalmic instrument designed to examine the interior of the eye allowing the examiner to clearly see the details of the retina and other structures/media.	B	IS/ISO 10942 : 2006
101.	Optical pachymeter	An ophthalmic, device that uses optics to measure the thickness of the cornea.	A	
102.	Orbital depressor	A hand-held ophthalmic surgical instrument used to displace tissue to facilitate examination of thesurrounding area in the orbital cavity during eye surgery.	A	
103.	Orbital rim prosthesis	An implantable ocular device used to reconstruct the floor of the bony cavity that contains the eyeball and its associated muscles, vessels, and nerves and is intended to house an artificial eye.	C	
104.	Perimeter	A diagnostic, ophthalmic instrument intended for assessing the extent of the patient's Peripheral visual field.	A	IS 18291
105.	Periocular/lacrimal retractor	A hand-held, non-self-retaining, ophthalmic surgical instrument intended to be used to separate periocular tissues and/or draw aside the margins of a periocular surgical wound during an ophthalmic intervention.	A	IS 6420 : 1989
106.	Phacoemulsification system	An assembly of ophthalmic devices intended to deliver energy through a dedicated hand piece tip, which is introduced through an incision made in the lens capsule, to perform	C	IS/IEC 80601-2-58 : 2016

		phacoemulsification.		
107.	Phorometer	An ophthalmic instrument intended to be used to test ocular balance.	A	
108.	Phoropter	A mechanical ophthalmic device that is used during an ophthalmic examination; Typically to determine a patient's prescription for glasses.	A	
109.	Pleoptophor	An ophthalmic instrument used for the treatment of eccentric eye fixation (casts in the eye) by dazzling the perimacular retina, thereby relatively enhancing the visual capabilities of the fovea.	A	
110.	Polatest	An ophthalmic device used for evaluating hidden (latent) squinting, i.e., when the Patient is not aware of the condition, and also when it cannot be seen.	A	
111.	Ptosis sling	A sterile implantable device intended for the surgical correction of ptosis.	C	
112.	Pupillograph	A graphic recorder used for recording the response of the pupil to reflected light. It is used for ophthalmic diagnostic purposes.	A	
113.	Pupillometer	An ophthalmic instrument used for measuring the width or diameter of the pupil.	A	
114.	Retinal tack	A non-bio absorbable, implantable device designed to permanently fix a detached retina to the underlying retinal pigment epithelium (RPE) during ophthalmic surgery.	C	
115.	Scleral buckling device	A device intended to be implanted on the sclera to compress the eye (scleral buckling) for the surgical Treatment of retinal detachment.	C	
116.	Scleral expansion implant	A device designed for implantation in the sclera to produce expansion by altering the position of the underlying ciliary muscle.	C	
117.	Scleral marker	A manual instrument used to indent or imprint the surface of the sclera during an ophthalmic surgical or Perioperative procedure.	B	
118.	Sclerotome	A hand-held manual ophthalmic surgical instrument that is knife-like in design and intended to be used to incise the sclera during a sclerotomy.	A	
119.	Scotometer	An instrument used for the recording and measuring of the areas of field of vision that is reduced, i.e., relative scotoma, or loss of sensitivity to light (absolute scotoma or Blind spots).	A	
120.	Surgical binoculars	A pair of lenses intended to be mounted onto a surgeon's spectacles to function as small telescope and provide a magnified image of	A	

		the visual field during patient examination or surgical intervention.		
121.	Symblepharon ring	An implantable device formed as a circular band used to help prevent the eyelid from Adhering to the eyeball.	C	
122.	Symblepharon ring	An implantable device formed as a circular band used to help prevent the eyelid from Adhering to the eyeball.	C	
123.	Synoptophor	A ophthalmic device used for the evaluation and training of a patient's binocular Function.	A	ISO 10944(MHD 5 (23545))
124.	Tachistoscope	An ophthalmic device designed to flash words or images at different speeds, for the purposes of Ophthalmic diagnostic testing.	A	
125.	Ultrasound pachymeter	An ophthalmic device designed to use ultrasound to measure the thickness of the cornea, and may in addition be designed to measure axial length and anterior chamber Depth.	B	ISO 22665
126.	Visual chart	An ophthalmic chart (Snellen chart) used in testing visual.	A	ISO 7921:2024
127.	Visual light box	A light viewing box that uses a translucent version of the ophthalmic chart (Snellen Chart) used for testing visual acuity.	A	
128.	Visual projector	An ophthalmic device intended to project an image on a screen to test visual acuity.	A	ISO 7921:2024
129.	Visual evoked-potential electrode	An electrical conductor intended to record changes in the electrical potential for the purpose of measuring Visual evoked responses.	A	
130.	Vitrectomy system	An assembly of ophthalmic devices intended to deliver energy through a dedicated Hand-held instrument typically used to treat diabetic vitreous hemorrhage, retinal detachment, epiretinal Membrane and macular hole.	C	IS/IEC 80601-2-58 : 2016
131.	Vitreous body prosthesis	A sterile bag/capsule intended to be implanted in the eye and filled with a fluid (not included) to replace the vitreous body and provide omnidirectional support of The retina for the treatment of severe retinal detachment.	C	
132.	Intraocular fluid	An intraocular fluid is a device consisting of a nongaseous fluid intended to be introduced into the eye to aid performance of surgery, such as to maintain anterior chamber depth, preserve tissue integrity, protect tissue from surgical trauma, or function as a tamponade during retinal Reattachment.	C	

133.	Intraocular gas	An intraocular gas is a device consisting of a gaseous fluid intended to be introduced into the eye to place pressure on a detached retina.	C	
134.	Intraocular lens guide	An intraocular lens guide is a deviceintended to be inserted into the eye during surgery to direct the insertion of an intraocular lens and be removed after insertion is completed.	B	
135.	Ophthalmic refractometer	An ophthalmic refractometer is an automatic AC-powered device that consists of a fixation system, a measurement and recording system, and an alignment system intended to measure the refractive power of the eye by measuring light reflexes from The retina.	B	IS/ISO 10342 : 2010

Annexure E

Sr no	Type of ballot	Reference Number	Title	Nominated Experts
1	SR	ISO 7998:2005 (Ed 2, vers 4)	Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary	1. Mr. B Shankar 2. Dr. Kuldeep Raizada 3. Ms.Harshada kadam
2	SR	ISO 8598-1:2014 (vers 2)	Optics and optical instruments — Focimeters — Part 1: General purpose instruments	Nil
3	SR	ISO 8612:2009 (Ed 2, vers 3)	Ophthalmic instruments — Tonometers	1. Mr. Rathinam Thyagrajan
4	SR	ISO 9342-2:2005 (vers 5)	Optics and optical instruments — Test lenses for calibration of focimeters — Part 2: Test lenses for focimeters used for measuring contact lenses	1. Mr. Sandeep Reddy
5	SR	ISO 9801:2009 (Ed 2, vers 3)	Ophthalmic instruments — Trial case lenses	1. Ms. Harshada Kadam
6	SR	ISO 10343:2014 (Ed 3, vers 2)	Ophthalmic instruments — Ophthalmometers	1. Mr. Rathinam Thyagrajan
7	SR	ISO 10940:2009 (Ed 2, vers 3)	Ophthalmic instruments — Fundus cameras	1. Mr. Rathinam Thyagrajan
8	SR	ISO 10944:2009 (Ed 2, vers 3)	Ophthalmic instruments — Synoptophores	1. Premnandhini Satgunam
9	SR	ISO 11979-6:2014 (Ed 3, vers 2)	Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing	1. Dr. Jolly Rohatgi 2. Ms. Harshada Kadam
10	SR	ISO 13212:2014 (Ed 3, vers 2)	Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life	1. Sandeep Reddy 2. Ms.Harshada Kadam
11	SR	ISO 13666:2019 (Ed 3)	Ophthalmic optics-Spectacle lenses — Vocabulary	1. Mr.B Shanakar
12	SR	ISO 14730:2014 (Ed 2, vers 2)	Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date	1. Ms.Savitri Sharma
13	SR	ISO 18529:2014 (vers 2)	Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms	1. Ms. Savitri sharma

Annexure F

S. No.	ISO/IEC Standard	Title	**Status of adoption (Adopted/Under adoption/Old edition adopted/Not adopted)**	Corresponding Indian Standard/Document No.
1	ISO 7998:2005	Ophthalmic optics — Spectacle frames — Lists of equivalent terms and vocabulary	Adopted	IS/ISO 7998 : 2005
2	ISO 8429:1986	Optics and optical instruments — Ophthalmology — Graduated dial scale	Adopted	IS 13783 : 1993/ISO 8429:1986
3	ISO 8596:2017	Ophthalmic optics — Visual acuity testing — Standard and clinical optotypes and their presentation	Adopted	IS/ISO 8596 : 2017
4	ISO 8596:2017/Amd 1:2019	Ophthalmic optics — Visual acuity testing — Standard and clinical optotypes and their presentation — Amendment 1	Adopted	IS/ISO 8596:2017
5	ISO 8598-1:2014	Optics and optical instruments — Focimeters — Part 1: General purpose instruments	Adopted	IS/ISO 8598-1 : 2014
6	ISO 8612:2009	Ophthalmic instruments — Tonometers	Adopted	IS/ISO 8612 : 2009
7	ISO 8624:2020	Ophthalmic optics — Spectacle frames — Measuring system and vocabulary	Adopted	IS 18378 : 2023/ISO 8624:2020
8	ISO 8980-1:2017	Ophthalmic optics — Uncut finished spectacle lenses — Part 1: Specifications for single-vision and multifocal lenses	Adopted	IS/ISO 8980-1 : 2017

9	ISO 8980-2:2017	Ophthalmic optics — Uncut finished spectacle lenses — Part 2: Specifications for power-variation lenses	Adopted	IS/ISO 8980-2 : 2017
10	ISO 8980-3:2022	Ophthalmic optics — Uncut finished spectacle lenses — Part 3: Transmittance specifications and test methods	Under Print	MHD/05/25458
11	ISO 8980-4:2006	Ophthalmic optics — Uncut finished spectacle lenses — Part 4: Specifications and test methods for anti-reflective coatings	Adopted	IS/ISO 8980-4 : 2006
12	ISO 8980-5:2005	Ophthalmic optics — Uncut finished spectacle lenses — Part 5: Minimum requirements for spectacle lens surfaces claimed to be abrasion-resistant	Adopted	IS/ISO 8980-5 : 2005
13	ISO 9342-1:2023	Optics and optical instruments — Test lenses for calibration of focimeters — Part 1: Reference lenses for focimeters used for measuring spectacle lenses	Adopted	IS 18583 (Part 1):2024
14	ISO 9342-2:2005	Optics and optical instruments — Test lenses for calibration of focimeters — Part 2: Test lenses for focimeters used for measuring contact lenses	Adopted	IS 18583 (Part 2):2024
15	ISO 9394:2012	Ophthalmic optics — Contact lenses and contact lens care products — Determination of biocompatibility by ocular study with rabbit eyes	Not Adopted	
16	ISO 9801:2009	Ophthalmic instruments — Trial case lenses	Adopted	IS/ISO 9801 : 2009

17	ISO 10322-1:2016	Ophthalmic optics — Semi-finished spectacle lens blanks — Part 1: Specifications for single-vision and multifocal lens blanks	Adopted	IS 17772 (Part 1) : 2022/ ISO 10322-1: 2016
18	ISO 10322-2:2016	Ophthalmic optics — Semi-finished spectacle lens blanks — Part 2: Specifications for progressive-power and degressive-power lens blanks	Adopted	IS 17772 (Part 2) : 2022/ISO 10322-2: 2016
19	ISO 10341:2012	Ophthalmic instruments — Refractor heads	Adopted	IS 18570 : 2024 ISO 10341 : 2012
20	ISO 10342:2010	Ophthalmic instruments — Eye refractometers	Adopted	IS/ISO 10342 : 2010
21	ISO 10343:2014	Ophthalmic instruments — Ophthalmometers	Adopted	IS 18572 : 2024 ISO 10343 : 2014
22	ISO 10936-2:2010	Optics and photonics — Operation microscopes — Part 2: Light hazard from operation microscopes used in ocular surgery	Adopted	IS 18581 (part 2): 2024/ ISO 10936-2 : 2010,MOD
23	ISO 10938:2016	Ophthalmic optics — Chart displays for visual acuity measurement — Printed, projected and electronic	Adopted	IS/ISO 10938 : 2016
24	ISO 10939:2017	Ophthalmic instruments — Slit-lamp microscopes	Adopted	IS/ISO 10939 : 2017
25	ISO 10940:2009	Ophthalmic instruments — Fundus cameras	Adopted	IS/ISO 10940 : 2009
26	ISO 10942:2022	Ophthalmic instruments — Direct ophthalmoscopes	Under Print	MHD/05/25356
27	ISO 10943:2023	Ophthalmic instruments — Indirect ophthalmoscopes	Under Print	MHD/05/25357
28	ISO 10944:2009	Ophthalmic instruments — Synoptophores	Adopted	IS 18571 : 2024 ISO 10944 : 2009
29	ISO 11380:1994	Optics and optical instruments — Ophthalmic optics — Formers	Not Adopted	

30	ISO 11381:2016	Ophthalmic optics — Spectacle frames — Screw threads	Not Adopted	
31	ISO 11978:2017	Ophthalmic optics — Contact lenses and contact lens care products — Labelling	Under Print	IS 18533:2024 ISO 11978: 2017
33	ISO 11979-1:2018	Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary	Adopted	IS/ISO 11979-1: 2018
34	ISO 11979-2:2024	Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods	Old version adopted	IS/ISO 11979-2 : 1999
35	ISO 11979-3:2012	Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods	Adopted	IS/ISO 11979-3 : 2012
36	ISO 11979-4:2008	Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information	Adopted	IS/ISO 11979-4 : 2008
37	ISO 11979-4:2008/Amd 1:2012	Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information — Amendment 1	Under Development	MHD/05/26614
38	ISO 11979-5:2020	Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility	Adopted	IS 18658 (PART 5) : 2024
39	ISO 11979-6:2014	Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability testing	Adopted	IS/ISO 11979-6 : 2014
40	ISO 11979-7:2024	Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations of intraocular lenses for the correction of aphakia	Under Development	MHD/05/25359
41	ISO 11979-8:2017	Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements	Adopted	IS/ISO 11979-8 : 2018

42	ISO 11979-10:2018	Ophthalmic implants — Intraocular lenses — Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes	Adopted	IS/ISO 11979-10 : 2018
43	ISO 11980:2012	Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations	Not Adopted	
44	ISO 11981:2017	Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses	Not Adopted	
45	ISO 11986:2017	Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release	Adopted	IS/ISO 11986 : 2017
46	ISO 11987:2012	Ophthalmic optics — Contact lenses — Determination of shelf-life	Not Adopted	
47	ISO 12865:2006	Ophthalmic instruments — Retinoscopes	Adopted	IS/ISO 12865 : 2006
48	ISO 12866:1999	Ophthalmic instruments — Perimeters	Adopted	IS 18291 : 2023/ISO 12866:1999+AMD 1:2008
49	ISO 12866:1999/Amd 1:2008	Ophthalmic instruments — Perimeters — Amendment 1	Adopted	IS 18291 : 2023/ISO 12866:1999+AMD 1:2008
50	ISO 12867:2010	Ophthalmic instruments — Trial frames	Adopted	IS 18580 : 2024/ ISO 12867 : 2010
51	ISO 12870:2024	Ophthalmic optics — Spectacle frames — Requirements and test methods	Adopted	IS 18576 : 2024/ISO 12870 : 2016
52	ISO 13212:2014	Ophthalmic optics — Contact lens care products —	Not Adopted	

		Guidelines for determination of shelf-life		
53	ISO 13666:2019	Ophthalmic optics — Spectacle lenses — Vocabulary	Under Print	MHD/05/25337
54	ISO 14534:2011	Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements	Under Print	MHD/05/25343
55	ISO 14729:2001	Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses	Not Adopted	
56	ISO 14729:2001/Amd 1:2010	Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses — Amendment 1	Not Adopted	
57	ISO 14730:2014	Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date	Not Adopted	
58	ISO 14889:2013	Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses	Not Adopted	
59	ISO 14889:2013/Amd 1:2017	Ophthalmic optics — Spectacle lenses — Fundamental requirements for uncut finished lenses — Amendment 1	Not Adopted	
60	ISO 15004-1:2020	Ophthalmic instruments — Fundamental requirements and test	Adopted	IS 18638-1 ; 2024 ISO 15004-1 : 2020,MOD

		methods — Part 1: General requirements applicable to all ophthalmic instruments		
61	ISO 15004-2:2007	Ophthalmic instruments — Fundamental requirements and test methods — Part 2: Light hazard protection	Adopted	IS 18638-2 :2024 ISO 15004-2 : 2007
62	ISO 15253:2021	Ophthalmic optics and instruments — Optical and electro-optical devices for enhancing low vision	Adopted	IS 18584 : 2024
63	ISO 15752:2010	Ophthalmic instruments — Endoilluminators — Fundamental requirements and test methods for optical radiation safety	Adopted	IS 18642 : 2024/ ISO 15752 : 2010,MOD
64	ISO 15798:2022	Ophthalmic implants — Ophthalmic viscosurgical devices	Adopted	IS 18639:2024
65	ISO 16034:2002+ Cor 1	Ophthalmic optics — Specifications for single-vision ready-to-wear near- vision spectacles	Adopted	IS 18578 : 2024/ISO 16034 : 2002
67	ISO 16671:2015	Ophthalmic implants — Irrigating solutions for ophthalmic surgery	Adopted	IS/ISO 16671 : 2015
68	ISO 16671:2015/Amd 1:2017	Ophthalmic implants — Irrigating solutions for ophthalmic surgery — Amendment 1	Not adopted	
69	ISO 16672:2020	Ophthalmic implants — Ocular endotamponades	Adopted	IS 18614 : 2024/ISO 16672 : 2020
70	ISO 16971:2024	Ophthalmic instruments — Optical coherence tomograph for the posterior segment of the human eye	Adopted	IS 18585 : 2024 ISO 16971 : 2015
71	ISO 18189:2016	Ophthalmic optics — Contact lenses and contact lens care products — Cytotoxicity testing of contact lenses in combination with lens care	Adopted	IS 18575 : 2024/ ISO 18189 : 2016

		solution to evaluate lens/solution interactions		
72	ISO 18259:2014	Ophthalmic optics — Contact lens care products — Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms	Adopted	IS 18574 : 2024/ISO 18259 : 2014
73	ISO 18369-1:2017	Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications	Adopted	IS/ISO 18369-1 : 2017
74	ISO 18369-2:2017	Ophthalmic optics — Contact lenses — Part 2: Tolerances	Adopted	IS/ISO 18369-2 : 2017
75	ISO 18369-3:2017	Ophthalmic optics — Contact lenses — Part 3: Measurement methods	Adopted	IS/ISO 18369 -3: 2017
76	ISO 18369-4:2017	Ophthalmic optics — Contact lenses — Part 4: Physicochemical properties of contact lens materials	Adopted	IS/ISO 18369 -4: 2017
77	ISO/TR 18476:2017	Ophthalmic optics and instruments — Free form technology — Spectacle lenses and measurement	Not Adopted	
78	ISO 19045:2015	Ophthalmic optics — Contact lens care products — Method for evaluating Acanthamoeba encystment by contact lens care products	Not Adopted	
79	ISO/TR 19498:2015	Ophthalmic optics and instruments — Correlation of optotypes	Not Adopted	
80	ISO 19979:2018	Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses	Not Adopted	

81	ISO 19980:2021	Ophthalmic instruments — Corneal topographers	Adopted	IS 18613 : 2024/ISO 19980 : 2021
82	ISO/TR 20772:2018	Ophthalmic optics — Spectacle lenses — Short wavelength visible solar radiation and the eye	Not Adopted	
83	ISO/TR 20824:2007	Ophthalmic instruments — Background for light hazard specification in ophthalmic instrument standards	Not Adopted	
84	ISO/TR 21958:2019	Ophthalmic optics — Review of the test methods used to assess scratch and abrasion resistance of spectacle lenses	Adopted	IS 18577 : 2024/ ISO/TR 21958 : 2019
85	ISO 21987:2017	Ophthalmic optics — Mounted spectacle lenses	Under Print	MHD/05/25281
86	ISO 22665:2012	Ophthalmic optics and instruments - Instruments to measure axial distances in the eye	Adopted	IS 18586 : 2024 ISO 22665 : 2012
87	ISO/TR 22979:2017	Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications	Not Adopted	
88	ISO 24157:2008	Ophthalmic optics and instruments — Reporting aberrations of the human eye	Adopted	IS 18599 : 2024/ ISO 24157 :2008+AMD 1:2020
90	ISO/TR 28980:2007	Ophthalmic optics — Spectacle lenses — Parameters affecting lens power measurement	Not Adopted	
91	IEC 80601-2-58:2024	Medical electrical equipment — Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery	Adopted	IS/IEC 80601-2-58 : 2017 IEC 80601-2-58:2016

92	IEC 80601-2-58:2014/Amd 1:2016	Medical electrical equipment — Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery — Amendment 1: Proposed Horizontal Standard	Adopted	IS/IEC 80601-2-58 : 2016 IEC 80601-2-58:2016
93	ISO 7921:2024	Ophthalmic optics and instruments Near reading charts	Adopted	IS 18919:2024

Annexure G
Review for Pre-2000

S. No.	IS Number	IS Title	Last Reaffirmation Year	Due Date	BIS Secretariat recommendation
1.	IS 10058 : 1985	Specification For Forceps, Fixation, Graefe's Pattern (Modified) (First Revision)	2017	December, 2022	Revision and reaffirm
2.	IS 10045 : 1981	Specification For Punch, Lacrymal Bone, Beyer's Pattern	2018	December, 2023	Revision and reaffirm
3.	IS 10009 : 1981	Specification For Breaker And Holder, Razor Blade, Barraquer's Pattern	2018	December, 2023	Withdraw
4.	IS 10389 : 1983	Specification For Fixation Hook, Eye, Guthrie's Pattern	2018	December, 2023	Withdraw
5.	IS 10390 : 1983	Specification for muscle hook	2018	December, 2023	Revision and reaffirm
6.	IS 10408 : 1983	Specification For Spatula, Eye, Green's Pattern	2013	December, 2018	Revision
7.	IS 10847 : 1984	Specification for Speculum with Screw Adjustment, Eye, Right and Left, Arruga's Pattern	2019	December, 2024	Revision
8.	IS 11244 : 1985	Specification for trephine, bone lacrimal with handle	2017	December, 2022	Withdraw
9.	IS 13783 : 1993 IS0 8429 : 1986	Optics and optical instruments - Ophthalmology - Graduated dial scale	2022	December, 2027	reaffirm
10	IS 4569 (Part 1) : 1985	Specification for scissors, eye: Part 1 corneal (Second Revision)	2017	December, 2022	Revision and reaffirm
11	IS 4569 (Part 2) : 1985	Specification for scissors, eye: Part 2 conjunctival, blunt and sharp - Point scissors (Second Revision)	2017	December, 2022	Revision and reaffirm
12.	IS 4569 (Part 3) : 1985	Specification for scissors, eye: part 3 scissors, tenotomy (Second Revision)	2017	December, 2022	Revision and reaffirm
13.	IS 4569 (Part 4) : 1985	Specification For Scissors, Eye Part 4 Scissors, Enucleation (Second Revision)	2017	December, 2022	Revision and reaffirm

14.	IS 4569 (Part 5) : 1985	Specification For Scissors, Eye Part 5 Scissors, Spring Action, Vanna's Pattern (Modified) (Second Revision)	2017	December, 2022	Revision and reaffirm
15.	IS 4569 (Part 6) : 1985	Specification For Scissors, Eye Part 6 Scissors, Iris (Second Revision)	2017	December, 2022	Revision and reaffirm
16.	IS 4790 : 1989	Eye Surgery Instruments - Knife, Corneal Splitting, Lang's And Tooke's Pattern (Modified) Specification (Second Revision)	2018	December, 2023	withdaw
17.	IS 5157 : 1981	Specification for forceps, eye, Iris (First Revision)	2018	December, 2023	Revision and reaffirm
18.	IS 5367 : 1969	Specification For Forceps, Eye, Strabismus, For Advancement (Prince's And Worth's Patterns)	2017	December, 2022	Revision and reaffirm
19.	IS 5722 : 1970	Specification For Hook, Eye, Iris (Tyrrell's Pattern)	2018	December, 2023	Withdraw
20.	IS 6420 : 1989	Eye Surgery Instruments - Retractor, Eye Lachrymal Sac, Muller's Pattern (Modified) - Specification (First Revision)	2013	December, 2018	Revision and reaffirm
21.	IS 7734 : 1975	Specification For Forceps, Eys, Peripheral Iridectomy, Traquair's Pattern	2018	December, 2023	Withdraw
22.	IS 7758 : 1975	Specification For Curette, Eye, Evacuation, Moorfield's Pattern	2018	December, 2023	Wihdraw
23.	IS 7762 : 1975	Specification for hook, eyelid	2018	December, 2023	Revision /Withdraw
24.	IS 7767 : 1975	Specification For Spatula, Eye, Cyclodialysis, Sinclair's Pattern	2018	December, 2023	Withdraw
25.	IS 7786 : 1975	Specification For Retractor, Eyelid, Desmarre's Pattern	2018	December, 2023	Revision
26.	IS 8106 : 1976	Specification For Needle Holder, Eye, Kalt's Pattern	2013	December, 2018	Revision
27.	IS 8109 : 1976	Specification For Needle Holder, Eye, Castroviejo's Pattern	2013	December, 2018	Revision
28.	IS 8181 : 1976	Specification for repositor, Iris	2013	December, 2018	Revision

29.	IS 8771 : 1985	Specification For Needle Holder, Eye, Scissors And Forceps Combined, Castroviejo's Pattern (Modified) (First Revision)	2017	December, 2022	Withdraw
30.	IS 8772 : 1985	Specification For Needle Holder, Eye, Barraquer's Pattern (Modified) (First Revision)	2017	December, 2022	Revision and reaffirm
31.	IS 8773 : 1985	Specification For Dissector, Lacrimal Sac, Lang's Pattern (Modified) (First Revision)	2017	December, 2022	Revision and reaffirm
32.	IS 8810 : 1985	Specification For Rougine For Lacrimal Sac, Rollet's Pattern (Modified) (First Revision)	2017	December, 2022	Withdraw
33.	IS 9061 : 1989	Eye Surgery Instruments - Dilators, Punctum, Wilder's Pattern (Modified) - Specification (First Revision)	2018	December, 2023	Revision and reaffirm
34.	IS 9062 : 1987	Specification For Probes, Lacrimal, Bowman's Pattern (Modified) (First Revision)	2018	December, 2023	Revision and reaffirm
35.	IS 9134 : 1987	Specification For Trephine, Corneal, Castroviejo's Pattern (Modified) (First Revision)	2018	December, 2023	Revision and reaffirm
36.	IS 9329 : 1987	Specification For Speculum, Eye, Clark's Pattern (Modified) (First Revision)	2018	December, 2023	Revision and reaffirm
37.	IS 9378 : 1987	Specification For Speculum, Eye, Castroviejo's Pattern (Modified) (First Revision)	2018	December, 2023	Revision and reaffirm
38.	IS 9688 : 1992	Eye surgery instruments - Hooks, strabismus - Specification (first revision)	2018	December, 2023	Revision and reaffirm
39.	IS 9983 : 1981	Specification for wire vectis and lens expressor, eye	2018	December, 2023	Revision and reaffirm

Annexure H

Due for review in 2025-2026

S. No	IS	Title	BIS Secretariat Remark
1.	IS/ISO 11979- Part 1 : 2018	Ophthalmic implants Intraocular lenses Part 1:Vocabulary First Revision	Reaffirm Due to base standard is not updated in ISO
2.	IS/ISO 11979 Part 7 : 2018	Ophthalmic implants Intraocular lenses Part 7: Clinical investigations of intraocular lenses for the correction of aphakia First Revision	Under development MHD/05/25359. Base version is updated as ISO 11797-7:2024
3.	IS/ISO 11979- Part 10 : 2018	Ophthalmic implants Intraocular lenses Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes First Revision	Reaffirm Due to base standard is not updated in ISO .

BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

AGENDA

Working Group	Meeting No	Date, Day & Time
Amendment working Group for Indian standards (MHD 05)	1st	24 October 2024, Friday , 3:00 PM

via Webex platform

Meeting Link: https://bismanak.webex.com/bismanak/j.php?MTID=m6232be809fbf2e68ea4406a010642619

Meeting Number: 2517 249 4506

Password: Mhd@05

Convener	Mr. Balachandar Settu In-personal Capacity
Member Secretary	Ms. Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

0.2 OPENING REMARKS BY CONVENER

ITEM 1 Discussion points

1.1 Discussion on the cross-referencing standards of IS/ISO 8612, IS/ISO 10342, and IS/ISO 18291, as outlined in the CMD email attached in Annex A.

Annexure A

Dear Sir,

This has reference to the AIF applications of Ophthalmic Instruments.
Currently, three AIF Applications as per IS /ISO 8612, IS / ISO 10342 & IS / ISO 18291 are under process with CMD-III.

The Standards referred above have cross referred the general requirements as per ISO 15004 (Part 1). However, ISO 15004 (Part 1) is not adopted by MHD. Instead, ISO 15004 (Part 1) has been modified and adopted as modified version IS 18638 (Part 1): 2024.

MHD is therefore requested to kindly clarify, if IS 18638 (Part 1): 2024 can be referred wherever ISO 15004 (Part 1) is referred. If so, MHD is requested to kindly issue an amendment that IS 18638 (Part 1) should be referred wherever ISO 15004 (Part 1) has been cross referred in the product standard (for eg. IS /ISO 8612, IS / ISO 10342 & IS / ISO 18291).

BUREAU OF INDIAN STANDARDS

MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

MINUTES

Working Group		Meeting No	Date, Day & Time
Amendment working Group for Indian standards (MHD 05)		1st	24 October 2024, Friday , 3:00 PM
Convener	Mr. Balachandar Settu In-personal Capacity		
Member Secretary	Ms. Harshada Ganesh Kadam Scientist B/ Assistant Director, Bureau of Indian Standards		

The list of participants is attached in Annex A

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

Ms Harshada Kadam the Member Secretary of MHD 05 welcomed the members to the 1st meeting of the Amendment Working Group for Indian standards. She appreciated the members present for sparing their valuable time participating in this meeting. The meeting commenced with the introduction of the members

0.2 OPENING REMARKS BY CONVENER

The Convener extended a warm welcome to the Member Secretary, Ms. Harshada Kadam, and all the members of the Working Group. He appreciated the members' involvement in the Amendment Working Group for Indian Standards.

ITEM 1 DISCUSSION POINTS

1.1 The working group deliberated on the cross-referencing standards of IS/ISO 8612, IS/ISO 10342, and IS/ISO 18291 and decided to issue the amendment for these standards as ISO 15004 (Part 1), which has been adopted as a modified version IS 18638 (Part 1): 2024.

Annexure A

List of participants:

Sr. No	Organization	Member
1.	In –Personal Capacity	Mr. Balachandar Settu
2.	L V Prasad Eye Institute, Hyderabad	Mr. Rathinam Thyagarajan
3.		Dr. PremNandhini Satgunam

BIS Directorate:

Sr. No	Name
1	Ms. Harshada Kadam , Scientist-B/ Assistant Director ,MHD