

BUREAU OF INDIAN STANDARDS
MEDICAL EQUIPMENT AND HOSPITAL PLANNING DEPARTMENT (MHD)

MINUTES

Sectional Committee		Meeting No	Date, Day & Time
Ophthalmic Instruments and Appliances Sectional Committee, (MHD 05)		18th	02 September 2024, Monday, 3:00 PM
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		

The List of Participants is attached in [Annex A](#)

ITEM 0 GENERAL

0.1 WELCOME ADDRESS BY MEMBER SECRETARY

Ms. Harshada Kadam the new Member Secretary of MHD 05 welcomed the members to the 18th meeting of the Ophthalmic Instruments and Appliances Sectional Committee. She also acknowledged the previous member secretary Mr Karthik Reddy for his immense contribution.

She appreciated the members present for sparing their valuable time to participate in this meeting. The meeting commenced with the introduction of the members

0.2 OPENING REMARKS BY CHAIRPERSON

The Chairperson extended a warm welcome to the Member Secretary Ms. Harshada Kadam and all the members of the committee, expressing the committee's commitment to providing her with maximum support. She acknowledged the outstanding contributions of the previous member secretary, Mr. Karthik Reddy. Emphasising the need for active participation and fruitful discussions among members, she underscored the importance of professionalism and a comprehensive perspective in decision-making. She then invited the Member Secretary to commence the proceedings.

ITEM 1 CONFIRMATION OF MINUTES OF THE PREVIOUS MEETING

- 1.1 The Committee formally confirmed the minutes of the last meeting of the Ophthalmic Instruments and Appliances Sectional Committee, (MHD 05) held on 13th May 2024

ITEM 2 SCOPE AND COMPOSITION OF SECTIONAL COMMITTEE

- 2.1 The Committee noted the Item 2.1 of the agenda.
- 2.2 The committee noted the Item 2.2 of the agenda
- 2.3 The committee noted the Item 2.3 of the agenda

ITEM 3 DRAFT STANDARDS / AMENDMENTS FOR FINALIZATION

- 3.1 The committee noted the Item 3.1 of the agenda

ITEM 4 DRAFT STANDARDS/AMENDMENTS FOR APPROVAL FOR WIDE CIRCULATION

- 4.1 The Committee consider the proposal to adopt the following Standards which may considered for be wide circulated for one Month.

Sl. No.	Document No./ Standard No.	Title	Justification
1.	ISO 11380:1994	Optics and optical instruments - Ophthalmic optics — Formers	The Committee reviewed the ISO standard & observed that ISO 11380 and ISO 11381 are cross referred in IS 18576:2024 “Ophthalmic optics Spectacle frames Requirements and test methods” wherever compliance requirements have been specified.
2.	ISO 11381:2016	Ophthalmic optics — Spectacle frames — Screw threads	
3.	ISO 11980:2012	Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations	The Committee reviewed the ISO standard and observed that ISO 11980, ISO 11987, ISO 13212, ISO 14729:2001+ Amd 1 and ISO 14730 are cross referred in IS 18864 :2024 “Ophthalmic optics
4.	ISO 11987:2012	Ophthalmic optics — Contact lenses — Determination of shelf-life	
5.	ISO 13212:2014	Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life	
6.	ISO 14729:2001+	Ophthalmic optics — Contact lens care products —	

	Amd 1:2010	Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses	Contact lenses and contact lens care products Fundamental requirements” wherever compliance requirements have been specified.
7.	ISO 14730:2014	Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date	
8.	ISO 19979:2018	Ophthalmic optics — Contact lenses — Hygienic management of multipatient use trial contact lenses	The committee deliberated and observed that the standard is important from the point of view of hygienic management of multipatient use trial contact lenses.
9.	ISO/TR 20772:2018	Ophthalmic optics — Spectacle lenses — Short wavelength visible solar radiation and the eye	The committee deliberated and observed that the standard is important as it describes the effect of visible solar radiation on human eye
10.	ISO/TR 22979:2017	Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications	The committee reviewed and observed that ISO/TR 22979 is cross referred in IS 18658 (Part 5) :2024 “Ophthalmic implants Intraocular lenses Part 5:Biocompatibility” wherever references to this standard is made for evaluation of intraocular lenses
11.	ISO 11981:2017	Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses	The committee deliberated and observed that ISO 11981 is an important product as it is intended to accessing the physical compatibility of contact lens care products with contact lens.

4.2 The committee deliberated and approved the following document for circulation as a Preliminary Draft.

<i>Sr No</i>	<i>Title</i>
1.	Ophthalmic Microsurgical Blades (for Single Use)- Requirements and Test Methods

4.2.1. The Committee deliberated and decided to circulate the Following draft document for the period of 30 days via email and if no comments are received within 30 days, then the draft document will be circulated as a Preliminary draft with the approval of the chairperson.

Sr. No	Title
1.	Ophthalmic Scan A and B

4.3 The Committee noted Item 4.3 of the agenda.

ITEM 5 DRAFT UNDER PREPARATION

5.1 The Committee noted the Item 5.1 of the agenda.

5.2 Commenting on P-Drafts by Members of Technical Committee

5.2.1 The Committee noted the Item 5.2.1 of the agenda.

5.2.2 The Committee noted the Item 5.2.2 of the agenda.

5.2.3 The Committee noted the Item 5.2.3 of the agenda.

ITEM 6 COMMENTS ON PUBLISHED STANDARDS

6.1 The Committee noted the Item 6.1 of the agenda.

ITEM 7 NEW SUBJECTS

7.1 The Committee noted the Item 7.1 of the agenda.

7.2 The Committee deliberated and decided to formulate the new Indigenous Standard for the following subject as per the list of CDSCO.

Sr No	Subject
1	Donor Cornea Container

7.2.1. The committee deliberated and requested the Member Secretary to circulate the list of CDSCO New topics in the Committee for period of 15 days for further deliberation.

ITEM 8 TECHNICAL ISSUES

8.1 The committee deliberated and decided to formulate the Working Group for the issues

of cross-reference standards in published standards.

Structure of the Amendment working group:

Sr No	Name	Role
1.	Mr. Balachandra settu	Convener
2.	Mr. B. Shankar	Expert
3.	Ms. Premnandini	Expert
4.	Mr. Rathinager	Expert

ITEM 9. INTERNATIONAL ACTIVITIES

9.1 Participating (P) Membership in ISO/IEC

9.1.1 The Committee noted the Item 9.1.1 of the agenda.

9.1.2 The Committee noted the Item 9.1.2 of the agenda.

9.2 Participation of Working Group Experts in ISO Technical Committees

9.2.1 The Committee noted the Item 9.2.1 of the agenda.

9.2.2 The Committee noted the Item 9.2.2 of the agenda.

9.3 Identification of Working Project Experts in ISO Technical Committees

9.3.1 The committee deliberated and nominated experts in the following projects. the list of projects and nominated experts is attached in the [Annex B](#)

9.3.2 The Committee noted the Item 9.3.2 of the agenda.

9.3.3 The Committee deliberated and nominated the following Members in the respective panels as Experts:

- 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

9.3.4 The Committee deliberated and approved the following Indian Delegations for ISO/TC 172/SC 7 "Ophthalmic optics and instruments" meetings scheduled to be held from 18 November 2024 to 22 November 2024 in Minato City, Japan.

- a) Dr. Jolly Rohatgi, Chairperson of MHD 05
- b) Ms. Harshada Ganesh Kadam, Member Secretary of MHD 05.

9.3.5. The Committee deliberated and approved the following Indian Delegations for ISO/TC 172/SC 7 "Ophthalmic optics and instruments" meetings scheduled to be held on 28 Oct 2024, virtually.

- a) Dr. Jolly Rohatgi, Chairperson of MHD 05
- b) Mr. Dattatreya Hegde
- c) Mr. Shankar b
- d) Mr. Balachandra settu
- e) Mr. Rathinam Thyagarajan.
- f) Mr. Rajiv Raman
- g) Ms.Harshada Kadam, Member Secretary of MHD 05

9.4 Harmonization of Indian Standards with International Standards

Sl. No.	Document No./ Standard No.	Title	Justification
1.	ISO 11979-4:2008/Amd 1:2012	Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information — Amendment 1	The committee deliberated and decided to adopt the Amendment of the ISO 11979-4 due to base standard is already adopted as a IS standard

ITEM 10. PROGRAMME OF WORK

10.1 The Committee noted the Item 10.1 of the agenda.

10.2 The Committee noted the Item 10.2 of the agenda.

ITEM 11. REVIEW OF INDIAN STANDARDS

11.1 Review of Pre-2000 Standards

11.1.1 The committee deliberated and reviewed the list of Pre-2000 standards and decided to Circulate all pre-2000 standards for the period of 45 days, after the completion of the circulation period decision will be taken via email with approval of the chairperson.

A list of Pre-2000 standards is attached in [Annex C](#).

11.2.2 The Committee reviewed and decided to withdraw the following standards:

Sr.No	IS Number & Title	Remarks
1.	IS 10696:1983 - Specification for round segment fused bifocal blanks	The Committee Deliberated and decided to withdraw these standards as per the 17 th meeting discussion and all these standards are obsoleted.
2.	IS 4382:1967- Specification for Non-Tinted Ophthalmic Glass	
3.	IS 6472:1971 - General requirements for tinted ophthalmic glass	
4.	IS 8260-1:1976 - Glossary of terms relating to ophthalmic lenses and spectacle frames: Part 1 ophthalmic lenses	

11.2 Review of Standards as per 5-year cycle

11.2.1 The Committee noted the Item 11.2.1 of the agenda.

11.2.2 The Committee noted the Item 11.2.2 of the agenda.

11.2.3 The Committee noted IS/ISO 10942:2006, revision is under development as an MHD/05/25356.

ITEM 12 ISSUES ARISING OUT OF THE PREVIOUS MEETINGS

The Committee noted the Item 12 of the agenda.

ITEM 13 DATE AND PLACE OF NEXT MEETING

13.1 As per the approved Annual Meeting Calendar for 2024-25, the next meeting of MHD 05 is scheduled on 9th Dec 2024.

ITEM 14 ANY OTHER BUSINESS

The Committee noted the Item 14 of the agenda.

Annexure- A

(Item 0)

List of Participants:

Sr. No	Organization	Member Name
1.	University College of Medical Sciences, New Delhi	Dr. Jolly Rohatgi (Chairperson)
2.	Akriti Ophthalmic Private Limited, Hyderabad	Dr. Kuldeep Raizada
3.	Appasamy Associates, Chennai	Mr. Rajesh Candamourty
4.	Aravind Eye Hospital, Madurai, Tamil Nadu, India	Dr. Shivakumar. C
5.	AuroLab, Madurai	Mr. R. Krishna Kumar
6.	Carl Zeiss India (Bangalore) India Private Limited, Bangalore	Mr. Dattatraya Hegde
7.	Central Drugs Standard Control Organization, New Delhi	Mr. Aseem Sahu
		Ms. Shyamni Sasidharan
		Mr. Gulhane Akshay Dinkar
8.	Dr Rajendra Prasad Centre for Ophthalmic Sciences, New Delhi	Dr. J.S. Titiyal
9.	Iscon Surgicals Limited, Jodhpur	Mr. Narendra Kumar Jain
10.	Kalam Institute Of Health Technology, Vishakhapatnam	Mr. Kanhu Lenka
11.	L V Prasad Eye Institute, Hyderabad	Mr. Rathinam Thyagarajan
		Dr. Prem Nandhini Satgunam
		Mr. Nabeel Quadri
12.	Sankara Nethralaya, Chennai	Dr. Prof. Rajiv Raman
13.	In Personal Capacity	Mr. Balachandar Settu
14.	In Personal Capacity	Mr. Shankar Balasubramanian

Annexure B

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 C
Review for Pre-2000

S. No	IS No.	TITLE
1.	IS 10045 : 1981Reviewed In : 2018	Specification For Punch, Lacrymal Bone, Beyer's Pattern
2.	IS 10009 : 1981Reviewed In : 2018	Specification For Breaker And Holder, Razor Blade, Barraquer's Pattern
3.	IS 10389 : 1983Reviewed In : 2018	Specification For Fixation Hook, Eye, Guthrie's Pattern
4.	IS 10390 : 1983Reviewed In : 2018	Specification for muscle hook
5.	IS 10408 : 1983Reviewed In : 2013	Specification For Spatula, Eye, Green's Pattern
6.	IS 10847 : 1984Reviewed In : 2019	Specification for Speculum with Screw Adjustment, Eye, Right and Left, Arruga's Pattern
7.	IS 11244 : 1985Reviewed In : 2017	Specification for trephine, bone lacrimal with handle
8.	IS 13783 : 1993ISO 8429 : 1986 Reviewed In : 2022	Optics and optical instruments - Ophthalmology - Graduated dial scale
9.	IS 4569 (Part 1) : 1985Reviewed In : 2017	Specification for scissors, eye: Part 1 corneal (Second Revision)
10.	IS 4569 (Part 2) : 1985Reviewed In : 2017	Specification for scissors, eye: Part 2 conjunctival, blunt and sharp - Point scissors (Second Revision)
11.	IS 4569 (Part 3) : 1985Reviewed In : 2017	Specification for scissors, eye: part 3 scissors, tenotomy (Second Revision)
12.	IS 4569 (Part 4) : 1985Reviewed In : 2017	Specification For Scissors, Eye Part 4 Scissors,Enucleation (Second Revision)
13.	IS 4569 (Part 5) : 1985Reviewed In : 2017	Specification For Scissors, Eye Part 5 Scissors, Spring Action, Vanna's Pattern (Modified) (Second Revision)
14.	IS 4569 (Part 6) : 1985Reviewed In : 2017	Specification For Scissors, Eye Part 6 Scissors, Iris (Second Revision)
15.	IS 4790 : 1989Reviewed In : 2018	Eye Surgery Instruments -Knife, Corneal Splitting, Lang's And Tooke's Pattern (Modified) Specification (Second Revision)
16.	IS 5157 : 1981Reviewed In : 2018	Specification for forceps, eye, Iris (First Revision)
17.	IS 5367 : 1969Reviewed In : 2017	Specification For Forceps, Eye, Strabismus, For Advancement (Prince's And Worth's Patterns)
18.	IS 5722 : 1970Reviewed In : 2018	Specification For Hook, Eye, Iris (Tyrrell's Pattern)
19.	IS 6420 : 1989Reviewed In : 2013	Eye Surgery Instruments - Retractor, Eye Lachrymal Sac, Muller's Pattern (Modified) - Specification (First Revision)
20.	IS 7734 : 1975Reviewed In : 2018	Specification For Forceps, Eys, Peripheral Iridectomy, Traquair's Pattern

21.	IS 7758 : 1975Reviewed In : 2018	Specification For Curette, Eye, Evacuation, Moorfield's Pattern
22.	IS 7762 : 1975Reviewed In : 2018	Specification for hook, eyelid
23.	IS 7767 : 1975Reviewed In : 2018	Specification For Spatula, Eye, Cyclodialysis, Sinclair's Pattern
24.	IS 7786 : 1975Reviewed In : 2018	Specification For Retractor, Eyelid, Desmarre's Pattern
25.	IS 8106 : 1976Reviewed In : 2013	Specification For Needle Holder, Eye, Kalt's Pattern
26.	IS 8109 : 1976Reviewed In : 2013	Specification For Needle Holder, Eye, Castroviejo's Pattern
27.	IS 8181 : 1976Reviewed In : 2013	Specification for repositor, Iris
28.	IS 8771 : 1985Reviewed In : 2017	Specification For Needle Holder, Eye, Scissors And Forceps Combined, Castroviejo's Pattern (Modified) (First Revision)
29.	IS 8772 : 1985Reviewed In : 2017	Specification For Needle Holder, Eye, Barraquer's Pattern (Modified) (First Revision)
30.	IS 8773 : 1985Reviewed In : 2017	Specification For Dissector, Lacrimal Sac, Lang's Pattern (Modified) (First Revision)
31.	IS 8810 : 1985Reviewed In : 2017	Specification For Rougine For Lacrimal Sac, Rollet's Pattern (Modified) (First Revision)
32.	IS 9061 : 1989Reviewed In : 2018	Eye Surgery Instruments - Dilators, Punctum, Wilder's Pattern (Modified) - Specification (First Revision)
33.	IS 9062 : 1987Reviewed In : 2018	Specification For Probes, Lacrimal, Bowman's Pattern (Modified) (First Revision)
34.	IS 9134 : 1987Reviewed In : 2018	Specification For Trephine, Corneal, Castroviejo's Pattern (Modified) (First Revision)
35.	IS 9329 : 1987Reviewed In : 2018	Specification For Speculum, Eye, Clark's Pattern (Modified) (First Revision)
36.	IS 9378 : 1987Reviewed In : 2018	Specification For Speculum, Eye, Castroviejo's Pattern (Modified) (First Revision)
37.	IS 9688 : 1992Reviewed In : 2018	Eye surgery instruments - Hooks, strabismus - Specification (first revision)
38.	IS 9983 : 1981Reviewed In : 2018	Specification for wire vectis and lens expressor, eye
39.	IS/ISO 11979-2 : 1999ISO 11979- 2:1999Reviewed In : 2017	Ophthalmic implants - Intraocular lenses: Part 2 optical properties and test methods

