Doc No.: MHD 05 (25343) WC
April 2024

BUREAU OF INDIAN STANDARDS

DRAFT FOR COMMENTS ONLY
(*Not to be reproduced without permission of BIS or used as an Indian Standard*)

भारतीय मानक मसौदा

नेत्र प्रकाशिकी – संपर्क लेंस और संपर्क लेंस देखभाल उत्पाद मौलिक आवश्यकताएं
(**ISO 14534:2011 MOD**)

Draft Indian Standard
Ophthalmic optics — Contact lenses and contact lens care products Fundamental requirements (ISO 14534:2011 MOD)

[ICS 11.040.70]

Ophthalmic Instruments and Appliances Sectional Committee, MHD 05	Last Date for Comments: 22nd May 2024

NATIONAL FOREWORD

(Adoption clause will be added later)

The text of ISO Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their respective places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Standard*	*Degree of Equivalence*
ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	IS 17932 (Part 1) : 2023 Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018 MOD)	Modified
ISO 11986, Ophthalmic optics — Contact lenses and contact lens care products — Determination of preservative uptake and release	IS/ISO 11986:2018, Ophthalmic optics Contact lenses and contact lens care products Determination of preservative uptake and release	Identical
ISO 14155, Clinical investigation of medical devices for human subjects — Good clinical practice	IS/ISO 14155 : 2020, Clinical investigation of medical devices for human subjects - Good clinical practice	Identical
ISO 14971, Medical devices — Application of risk management to medical devices	IS/ISO 14971 : 2019, Medical devices - Application of risk management to medical devices (First Revision)	Identical
ISO 15223-1, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements	IS/ISO 15223-1 : 2016, Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied Part 1 General Requirements (Second Revision)	Identical
ISO 18369-1, Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications	IS/ISO 18369 : 2017, Ophthalmic optics Contact lenses Part 1 Vocabulary classification system and recommendations for labeling specifications (First Revision)	Identical
ISO 18369-2, Ophthalmic optics — Contact lenses — Part 2: Tolerances	IS/ISO 18369 : 2017, Ophthalmic optics - Contact lenses Part 2: Tolerances (First Revision)	Identical
ISO 22442 (all parts), Medical devices utilizing animal tissues and their derivatives	IS/ISO 22442-1: 2015**,** Medical Devices Utilizing Animal Tissues and their Derivatives Part 1 Application of Risk Management,	Identical

IS/ISO 22442-2: 2015, Medical Devices Utilizing Animal Tissues and their Derivatives Part 2 Controls on Sourcing, Collection and Handling

IS/ISO 22442-3: 2007, Medical Devices Utilizing Animal Tissues and their Derivatives Part 3 Validation of the Elimination and/or Inactivation of Viruses and Transmissible Spongiform Encephalopathy (TSE) Agents

IS/ISO/TR 22442-4: 2010, Medical Devices Utilizing Animal Tissues and their Derivatives Part 4 Principles for Elimination and/or Inactivation of Transmissble Spongifrom Encephalopathy (TSE) Agents and Validation Assays for those Processes

The technical committee has reviewed the provisions of the following International Standard referred in this adopted standard and has decided that it is acceptable for use in conjunction with this standard:

International Standard	*Title*
ISO 11978	Ophthalmic optics — Contact lenses and contact lens care products — Information supplied by the manufacturer
ISO 11980	Ophthalmic optics — Contact lenses and contact lens care products — Guidance for clinical investigations
ISO 11987	Ophthalmic optics — Contact lenses — Determination of shelf-life
ISO 13212	Ophthalmic optics — Contact lens care products — Guidelines for determination of shelf-life
ISO14729:2001+ Amd.1:2010	Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses
ISO 14730	Ophthalmic optics — Contact lens care products — Antimicrobial preservative efficacy testing and guidance on determining discard date

In this Standard, reference to ISO 10993-1 has been modified to IS 17932 (Part 1) : 2023 which is a modified adoption of ISO 10993-1:2018.

This standard also makes a reference to the BIS Certification Marking of the product. Details of which is given in National Annex A

NATIONAL ANNEX A

(National Foreword)

A-1 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 BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

Note: The technical content of the document has not been included as it is identical with the corresponding ISO standard. For details, please refer to ISO 14534:2011 or kindly contact:

Head (MHD)
Bureau of Indian Standards
Manak Bhawan
9, Bahadur Shah Zafar Marg
New Delhi-110002
Email: hmhd@bis.gov.in; mhd@bis.gov.in

Scope

This International Standard specifies safety and performance requirements for contact lenses, contact lens care products, and other accessories for contact lenses.

This International Standard does not specify electrical safety and electromagnetic compatibility considerations that might arise from the use of electrical equipment in conjunction with contact lenses or contact lens care products**.**