

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 प्रत्यारोपण - इंद्राओकुलर लेंस
भाग 7 वाचाघात के सुधार के लिए इंद्राओकुलर लेंस की नैदानिक जांच
(ISO 11979-7:2024)

Draft Indian Standard

Ophthalmic implants — Intraocular lenses

**Part 7 Clinical investigations of intraocular lenses for the correction of
aphakia**
(ISO 11979-7:2024)

[ICS 11.040.70]

Ophthalmic Instruments and Appliances Sectional Committee,
MHD 05

Last Date for Comments:
23rd 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:

<i>International Standard</i>	<i>Corresponding Standard</i>	<i>Degree of Equivalence</i>
ISO 11979-1, Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary	IS/ISO 11979-1:2018, Ophthalmic implants Intraocular lenses Part 1: Vocabulary (First Revision)	Identical
ISO 11979-10, Ophthalmic implants — Intraocular lenses — Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes	IS/ISO 11979-10:2018, Ophthalmic implants Intraocular lenses Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes (First Revision)	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

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 11979-7:2024 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 document specifies the particular requirements for the clinical investigations of intraocular lenses that are implanted in the eye in order to correct aphakia.