***भारतीय मानक***

***Indian Standard***

**IS 11979 (Part 7) : 2024**

**ISO 11979-7 : 2024**

 [**Superseding**

 **IS/ISO 11979-7:2018;**

 **IS/ISO 11979- 9: 2006]**

**नेत्र अन्तःरोपण — अंतः कोशिकीय लेंस**

**भाग 7 नेत्र अन्तःरोपण के सुधार के लिए अंतःनेत्र लेंस की नैदानिक जांच**

***(दूसरा पुनरीक्षण)***

**Ophthalmic implants — intraocular lenses**

**Part 7 Clinical investigations of intraocular lenses for the correction of aphakia**

 ***(Second Revision)***

ICS 11.040.70

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भारतीय मानक ब्यूरो

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मानक भवन, 9 बहादुर शाह ज़फर मार्ग, नई दिल्ली - 110002

MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG

NEW DELHI - 110002

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**December 2024 Price Group X**

Ophthalmic Instruments and Appliances Sectional Committee, MHD 05

NATIONAL FOREWORD

This Indian Standard (Part 7) (Second Revision) which is identical with ISO 11979-7:2024, ‘Ophthalmic implants — Intraocular lenses Part 7 Clinical investigations of intraocular lenses for the correction of aphakia’ issued by the International Organization for Standardization was adopted by Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 2011 as IS/ISO 11979-7 : 2006 ‘Ophthalmic Implants — Intraocular Lenses Part 7 Clinical Investigations’. The first revision of this standard was published in 2021 as IS/ISO 11979-7 : 2018 Ophthalmic Implants — Intraocular Lenses Part 7 Clinical Investigations’. The second revision has been undertaken to align it with latest edition of ISO 11979-7.

This Indian standard supersedes IS/ISO 11979 Part 7: 2018 and IS/ISO 11979: Part 9: 2006 as ISO 11979-9:2006+Amd 1:2014 has been replaced by ISO 11979-7:2018, ISO 11979-7:2018 is replaced by latest edition of ISO 11979-7:2024. After publication of this standard IS/ISO 11979 Part 9: 2006 and IS/ISO 11979: Part 7: 2018 stands withdrawn.

This Indian Standard is published in seven parts. The other parts in this series are:

Part 1 Vocabulary

Part 2 Optical properties and test methods

Part 3 Mechanical properties and test methods

Part 4 Labelling and information

Part 5 Biocompatibility

Part 6 Shelf life and transport stability

Part 8 Fundamental requirements

Part 10 Phakic intraocular lenses

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:

1. Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and
2. 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 Indian Standard* | *Degree of Equivalence* |
| 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, Ophthalmic implants — Intraocular lenses — Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes | 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 |

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis shall be rounded off in accordance with IS 2: 2022 ‘Rules for rounding off numerical values (Second Revision)’. The number of significant places retained in the rounded off value should be same as that of the specified value in this standard.

**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 *Bureau of Indian Standards Act,* 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.