

ANSI Z80.29-2015

# American National Standard

*for Ophthalmics –  
Accommodative Intraocular Lenses*

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**ANSI<sup>®</sup>**  
**Z80.29-2015**

American National Standard  
for Ophthalmics –  
**Accommodative Intraocular Lenses**

Secretariat  
**The Vision Council**

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**American National Standards Institute, Inc.**

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### *Developed by*

The Accredited Committee Z80 for Ophthalmic Standards -

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**Foreword** (This foreword is not part of American National Standard ANSI Z80.29-2015.)

This standard contains five annexes. Annex A is normative and is considered part of the standard. Annexes B through E are informative and are not considered part of the standard.

Suggestions for improvement of this standard are welcome. They should be sent to the Vision Council, 225 Reinekers Lane, Suite 700, Alexandria, VA 22314.

This standard was processed and approved for submittal to ANSI by the Accredited Standards Committee on Ophthalmic Optics, Z80. Committee approval of this standard indicates general consensus but in no way implies that all committee members voted for approval. At the time it approved this standard, the Z80 Committee had the following members:

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Quido Cappelli, Vice-Chairman  
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The working group for Accomodative Intraocular Lenses, which fall under the Medical Ophthalmic Devices Subcommittee, had the following members who worked on the writing of this standard:

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## American National Standard for Ophthalmics –

# Accommodative Intraocular Lenses

## 1 Scope and purpose

This standard applies to any ocular implant whose primary indication is the correction of aphakia and is designed to provide vision over a continuous range of distances by affecting a change in the vergence power of the eye resulting from the implant design that changes eye optical power or implant position in response to a stimulus. For the purposes of this standard, these implants are referred to as accommodative intraocular lenses (AIOLs).

This standard addresses specific requirements for AIOLs that are not addressed in the normative references, and include vocabulary, optical properties and test methods, mechanical properties and test methods, labeling, biocompatibility, sterility, shelf-life and transport stability, and clinical investigations necessary for this type of device. As with any standard, alternative validated test methods may be used.

## 2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this American National Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this American National Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of the IEC and ISO maintain registers of currently valid International Standards.

ANSI Z80.7, *Ophthalmics – Intraocular lenses*

ISO 10993-2, *Biological evaluation of medical devices – Part 2: Animal welfare requirements*

ISO 10993-6, *Biological evaluation of medical devices – Part 6: Tests for local effects after implantation*

ISO 11979-1, *Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary*

ISO 11979-2, *Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods*

ISO 11979-3, *Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods*

ISO 11979-5, *Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility*

ISO 11979-7, *Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations*

ISO/DIS 11979-8, *Ophthalmic implants – Intraocular lenses – Part 8: Fundamental requirements*