American National Standard

for Ophthalmics –

Phakic Intraocular Lenses

ANSI Z80.13-2007 (R2012)

ANSI®
Z80.13-2007 (R2012)
Reaffirmation of
ANSI Z80.13-2007

American National Standard
for Ophthalmics –

Phakic Intraocular Lenses

Secretariat

The Vision Council

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American National Standard

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Foreword (This foreword is not part of American National Standard ANSI Z80.13-2007 (R2012).)

ANSI Z80.13-2007, Ophthalmics - Phakic intraocular lenses, was developed by a group of experts consisting of scientists, industrialists, government regulators and clinicians among them developers and/or manufacturers of such lasers. This standard applies to the physical and mechanical properties and performances as well as material biocompatibility and describes elements of clinical protocol to be used to assess the clinical performance of these devices with the crystaline lens in place to correct refractive errors. The standard also contains informative sections.

Suggestions for improvements of the standard are welcome. These should be sent to The Vision Council, 225 Reinkers Lane, Suite 700, Alexandria, VA 22314.

American National Standard
for Ophthalmics –

Phakic Intraocular Lenses

1 Scope and purpose

This standard applies to any intraocular lens (IOL) whose primary indication is the modification of the refractive power of a phakic eye. It does not include IOLs used to correct presbyopia or astigmatism.

This standard addresses the 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 applies to 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. 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 Z80.7-2002, *Ophthalmics – Intraocular lenses*

Good Laboratory Practices (GLP), U.S. Code of Federal Regulations, 21, Part 58

ISO 10993-2:1998, *Biological evaluation of medical devices – Part 2: Animal welfare requirements*

ISO 11979-1:1999, *Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary*

ISO 11979-2:1999, *Ophthalmic implants – Intraocular lenses – Part 2: Optical properties and test methods*

ISO 11979-3:1999, *Ophthalmic implants – Intraocular lenses – Part 3: Mechanical properties and test methods*

ISO 11979-5:1999, *Ophthalmic implants – Intraocular lenses – Part 5: Biocompatibility*

ISO 11979-6:2002, *Ophthalmic implants – Intraocular lenses – Part 6: Shelf-life and transport stability*

ISO 14155-1:2003, *Clinical investigation of medical devices - Part 1: General Requirements*

ISO 14155-2:2003, *Clinical investigation of medical devices - Part 2: Clinical investigation plans*