American National Standard

for Ophthalmics –

Multifocal Intraocular Lenses

ANSI Z80.12-2007 (R2012)

ANSI®
Z80.12-2007 (R2012)
Reaffirmation of
ANSI Z80.12-2007

American National Standard
for Ophthalmics –

Multifocal 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 Z80.12-2007 (R2012).)

ANSI Z80.12-2007, Ophthalmics - Multifocal 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 lenses. 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 for replacement of the cataractous lens to allow both near and distance vision. The standard contains eight annexes. Annex A is a normative annex and is considered as part of the text. All other annexes are informative and are not considered as part of the text.

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

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for Ophthalmics –

Multifocal Intraocular Lenses

1 Scope and purpose

This standard applies to any ocular implant whose primary indication is the correction of aphakia and whose optic is designed to provide simultaneous distance and near vision. For the purposes of this standard, these implants are referred to as multifocal intraocular lenses (MIOLs). This standard does not consider optics designed to provide astigmatic power correction. The term “near vision”, as used in this standard, includes useful vision at the distance of claimed benefit; e.g., near and/or intermediate distances.

This standard addresses specific requirements for MIOLs that are not addressed in the normative references, and includes 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. 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*

ISO 10993-2:1992, *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 11979-4:2000, *Ophthalmic implants – Intraocular lenses – Part 4: Labeling and information*

ISO 11979-7:2001, *Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations*

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*