American National Standard

for Ophthalmics –
Extended Depth of Focus
Intraocular Lenses

ANSI Z80.35-2018

ANSI®
Z80.35-2018

American National Standard
for Ophthalmics –

Extended Depth of Focus Intraocular Lenses

Sponsor

The Vision Council

Approved September 25, 2018
Published January 29, 2019

American National Standards Institute, Inc.

American National Standard

Approval of an American National Standard requires review by ANSI that the requirements for due process, consensus, and other criteria for approval have been met by the standards developer.

Consensus is established when, in the judgement of the ANSI Board of Standards Review, substantial agreement has been reached by directly and materially affected interests. Substantial agreement means much more than a simple majority, but not necessarily unanimity. Consensus requires that all views and objections be considered, and that a concerted effort be made towards their resolution.

The use of American National Standards is completely voluntary; their existence does not in any respect preclude anyone, whether he has approved the standards or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standards.

The American National Standards Institute does not develop standards and will in no circumstances give an interpretation of any American National Standard. Moreover, no person shall have the right or authority to issue an interpretation of an American National Standard in the name of the American National Standards Institute. Requests for interpretations should be addressed to the secretariat or sponsor whose name appears on the title page of this standard.

CAUTION NOTICE: This American National Standard may be revised or withdrawn at any time. The procedures of the American National Standards Institute require that action be taken periodically to reaffirm, revise, or withdraw this standard. Purchasers of American National Standards may receive current information on all standards by calling or writing the American National Standards Institute.

Developed by

The Accredited Committee Z80 for Ophthalmic Standards -

The Vision Council
Z80 Secretariat
225 Reinekers Lane
Suite 700
Alexandria, VA 22314

Published by

The Vision Council
225 Reinekers Lane
Suite 700
Alexandria, VA 22314

Printed in the United States of America

Contents

Page

Annexes

Page

Tables

Figures

Foreword (This foreword is not part of American National Standard ANSI Z80.35-2018.)

In 1985, the Z80 committee became an ANSI accredited standards committee. The scope of the Z80 committee is the development of standards for the field of ophthalmic optics.

The Z80.35 standard deals with extended depth of focus (EDF) intraocular lenses used to correct aphakia and provided extended range of focus. The Z80.35 committee originated from the Z80.7 committee on intraocular lenses. Intraocular lenses have become the most common functional prosthetic implanted in the world today. Reproducibility is such that these lenses are no longer meant to just restore basic visual function but are expected to achieve improved visual function. The Z80.35 standard addresses the additional requirements for a new generation of intraocular lenses that provide extended range of focus.

This standard contains six annexes. Annexes A and D are normative and considered part of this standard. Annexes B, C, E and F are informative and are not considered part of this standard.

Suggestions for improvement of this standard will be 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 Standards, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time it approved this standard, the Z80 Committee had the following members:

Carl Tubbs, Chairman
Neil Roché, Vice-Chairman
William J. Benjamin, O.D., Secretary
Michael Vitale, Secretariat

Organization Represented	*Name of Representative*
Advanced Medical Technology Association	Michael Pfleger
American Academy of Ophthalmology	Carl Tubbs
American Academy of Optometry	David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Steven Gedde
American Optometric Association	William Benjamin
American Society of Cataract and Refractive Surgery	Stephen Klyce
Contact Lens Institute	Stan Rogaski
Contact Lens Manufacturers Association	Martin Dalsing
Cornea Society	Michael Belin
Department of Veterans Affairs	John Townsend
Food & Drug Administration CDRH/Division	Don Calogero
Individual	Ralph Stone
Johnson & Johnson Vision	Priya Janakiraman
National Association of Optometrists & Opticians	Nick Mileti
Optical Laboratory Association	Steve Sutherlin
Opticians Association of America	Tom Hicks
Sunglass Association of America	Tibor Gross
The Vision Council	Michael Vitale
ISO TC 172/SC7	Michael Vitale

Individual Member

Ralph Stone

The subcommittee on Intraocular Lenses, which developed this standard, had the following members:

Carl Tubbs, SC4 Chair
Sanjeev Kasthurirangan, Z80.35 Chair
Raj Suryakumar, Clinical Leader
Charles Campbell, Optical Leader

Ophelia Biggs
Don Calogero
Carmen Canovas
Bruce Drum
Carrie Garufis
George Green
Gene Hilmantel
Andrew Jones
Michael Pfleger
Michael Simpson
Nicholas Tarantino
Eugenia Thomas
Steve Van Noy
Srividhya Vilupuru
Henk Weeber
Xin Wei

American National Standard
for Ophthalmics –

Extended Depth of Focus Intraocular Lenses

1 Scope and purpose

This standard applies to intraocular lenses (IOLs) whose function is the correction of aphakia, with extended range of focus above a defined functional visual acuity threshold to provide useful distance and intermediate vision with monotonically decreasing visual acuity from the best distance focal point.

This standard addresses specific requirements for Extended Depth of Focus Intraocular Lenses (EDF IOLs) 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 11979-4, *Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information*

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*

ISO/WD 11979-9, *Ophthalmic implants – Intraocular lenses – Part 9: Multifocal intraocular lenses*