

# American National Standard

*for Ophthalmics –  
Multifocal Intraocular Lenses*

---





**ANSI<sup>®</sup>**  
**Z80.12-2007 (R2017)**  
Reaffirmation of  
ANSI Z80.12-2007 (R2012)

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

Secretariat  
**The Vision Council**

Approved March 26, 2007  
Reaffirmed April 16, 2012  
Reaffirmed December 11, 2017

**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**CAUTION NOTICE:** This American National Standard may be revised or withdrawn at any time.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

Copyright © 2017 by The Vision Council  
All rights reserved.

No part of this publication may be reproduced in any form, in an electronic retrieval system or otherwise, without prior written permission of the publisher.

Printed in the United States of America

## Contents

	Page
Foreword .....	iv
<b>1</b> Scope and Purpose .....	1
<b>2</b> Normative references.....	1
<b>3</b> Definitions .....	2
<b>4</b> Physical requirements.....	2
4.1 Scope.....	2
4.2 Requirements.....	2
4.2.1 Tolerances and dimensions .....	2
<b>5</b> Optical requirements.....	2
5.1 Scope.....	2
5.2 Requirements.....	2
5.2.1 Optical characterization .....	2
5.2.2 Dioptric power .....	2
5.2.3 Imaging quality .....	3
5.2.4 Spectral transmittance .....	4
<b>6</b> Mechanical requirements.....	4
6.1 Scope.....	4
6.2 Requirements.....	4
6.2.1 Mechanical characterization .....	4
6.2.2 Mechanical testing .....	4
<b>7</b> Biocompatibility requirements .....	5
7.1 Scope.....	5
7.2 General guidelines .....	5
7.3 Biological test requirements.....	5
7.4 Physicochemical test requirements .....	5
<b>8</b> Sterility/package integrity requirements .....	6
8.1 Scope.....	6
8.2 Requirements.....	6
<b>9</b> Shelf-life and transport stability requirements.....	6
9.1 Scope.....	6
9.2 Requirements.....	6
<b>10</b> Clinical evaluation .....	6
10.1 Scope.....	6
10.2 Clinical investigation plan.....	6
<b>11</b> Labeling .....	7

	Page
<b>Annexes</b>	
<b>A</b>	<b>Optical characterization ..... 9</b>
A.1	General ..... 9
A.2	Optical characterization ..... 9
A.2.1	Theoretical evaluation..... 9
A.2.2	Optical testing ..... 9
<b>B</b>	<b>Non-ocular implantation test ..... 11</b>
<b>C</b>	<b>Clinical investigation ..... 12</b>
C.1	Objectives of the clinical investigation ..... 12
C.2	Design of the clinical investigation ..... 12
C.3	Accountability analysis..... 12
C.4	Subjects ..... 13
C.4.1	Study group ..... 13
C.4.2	Control group ..... 14
C.4.3	Inclusion and exclusion criteria ..... 14
C.4.3.1	Inclusion criteria ..... 14
C.4.3.2	Exclusion criteria..... 14
C.4.4	Enrollment of subjects ..... 14
C.5	Variables to be investigated..... 15
C.5.1	Visual acuity..... 15
C.5.2	Pupil size ..... 16
C.5.3	Lens stability ..... 16
C.5.4	Subject survey ..... 17
C.5.5	Defocus curves ..... 17
C.5.6	Fundus visualization ..... 18
C.5.7	Far contrast sensitivity ..... 18
C.5.8	Functional performance ..... 19
<b>D</b>	<b>MIOL modifications ..... 22</b>
D.1	Scope..... 22
D.2	Modifications ..... 22
D.2.1	Addition of a parent multifocal optic to a parent monofocal model .... 22
D.2.2	Modification of the geometry of a parent multifocal optic..... 23
<b>E</b>	<b>Labeling for MIOLs ..... 24</b>
E.1	Scope..... 24
E.2	Information to be found on the outer container ..... 24

	Page
E.3	Labeling for inner container and/or pouch..... 24
E.4	Physician package insert ..... 24
E.5	Patient labeling..... 25
<b>F</b>	Determination of sample sizes for the clinical investigation ..... 26
F.1	Safety and performance study ..... 26
F.2	Control sensitivity study ..... 26
F.3	Functional performance substudy ..... 28
<b>G</b>	Functional performance ..... 30
G.1	Objective ..... 30
G.2	Subjects ..... 30
G.3	Study design ..... 30
G.4	Apparatus..... 31
G.5	Response procedures and measurement methods ..... 32
G.6	Validation studies ..... 32
G.7	Data analysis..... 33
<b>H</b>	Bibliography ..... 34
<b>Tables</b>	
<b>C.1</b>	Accountability at each post-operative visit ..... 13
<b>C.2</b>	Recommended postoperative examination schedule ..... 20
<b>F.1</b>	Parameter definitions ..... 27
<b>F.2</b>	Normal quantiles to use in equations ..... 27
<b>Figure</b>	
<b>A.1</b>	Example of MTF through focus response for multiple pupil sizes ..... 10

**Foreword** (This foreword is not part of American National Standard ANSI Z80.12-2007 (R2017).)

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.

# American National Standard 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*