American National Standard

for Ophthalmics –
Contact Lens Care Products – Vocabulary, Performance Specifications, and Test Methodology

ANSI Z80.18-2016

ANSI®
Z80.18-2016
Revision of
ANSI Z80.18-2010

American National Standard
for Ophthalmics –

Contact Lens Care Products – Vocabulary, Performance Specifications, and Test Methodology

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 Z80.18-2016.)

The Z80 Committee for Ophthalmics was organized in 1956, and the committee's initial standard on ophthalmic lenses was issued in 1964. In the ensuing years the committee expanded its scope and organization into a number of subcommittees, each charged with specific areas of responsibility. One of these, The Subcommittee for Contact Lenses, has published two standards: Z80.18, Contact Lens Care Products - Vocabulary, Performance Specifications, and Test Methodology, and Z80.20, Contact Lenses - Standard Terminology, Tolerances Measurements and Physiochemical Properties, which are dutifully reviewed on a five-year basis to include any newly established information.

Since 1980, the Subcommittee for Contact Lenses has provided delegates to the International Standards Organization to represent the American Standards Institute's role (for the United States) in developing and approving contact lens and contact lens care products standards for the international community. In providing this service for ANSI it became apparent that the role of the delegates continued to require reaffirmation from the American community as a whole to support their input. Thus, in addition to providing information to the international forum the Subcommittee for Contact Lenses continues to process all available information through its ANSI network.

This latest version of Z80.18 meets that objective while ensuring that the US standard is in conformance with the International Standard. Thus, this revision of Z80.18 and future reviews or revisions of this standard will ensure that the continued participation of American delegates to ISO will be supported by an American standard that has received a consensus by the Z80 Committee for Ophthalmic standards in addition to other American interests.

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 Optics, Z80. Committee approval of this standard does not necessarily imply that all committee members voted for its approval. At the time of approval of this standard, the Z80 Committee consisted of the following members:

Thomas White, M.D., Chairman
Quido Cappelli, Vice-Chairman
William Benjamin, O.D., Secretary
Michael Vitale, Secretariat

Organization Represented	*Name of Representative*
Abbott Medical Optics	Leonard Borrmann
Advance Medical Technologies Association	Michael Pfleger
American Academy of Ophthalmology	Dr. Thomas White
American Academy of Optometry	Dr. David Loshin
American Ceramic Society	Lyle Rubin
American Glaucoma Society	Dr. Steven Gedde
American Optometric Association	Dr. Karl Citek
American Society of Cataract and Refractive Ophthalmology	Dr. Stephen Klyce
Contact Lens Institute	Stan Rogaski
Contact Lens Manufacturers Association	Quido Cappelli
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Federated Cornea Societies/ASCRS	Dr. Michael Belin
Food & Drug Administration	Don Calogero
National Association of Optometrists & Opticians	Nick Mileti
Optical Laboratory Association	Steve Sutherlin
Opticians Association of America	Tom Hicks
Sunglass Association of America	Tibor Gross
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U.S. TAG Leader to ISO TC 172/SC7	Michael Vitale

The working group that coordinated the development of this revision and harmonization with ISO Standards was headed by Mary Mowrey-McKee. As of the date of publication of this revision, the Subcommittee had the following active members:

Quido A. Cappelli, Chairman
(Contact Lens Manufacturers Association)

William J. Benjamin
(American Optometric Association)
Glenn Davies
(Bausch & Lomb, Inc.)
Paul Ludington
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Stan Rogaski
(Contact Lens Institute)

The individuals who worked on the revision of ANSI Z80.18 were:

William J. Benjamin
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Thomas White
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Contact Lens Care Products – Vocabulary, Performance Specifications, and Test Methodology

1 Scope

This American National Standard applies to contact lens care products (CLCP) which are marketed for use with hard (PMMA), rigid gas permeable (RGP), enhanced oxygen permeable materials, and soft hydrophilic contact lenses. These products are intended for use in the care of contact lenses: e.g. rinsing, storing, disinfection, conditioning, neutralization, cleaning, hydration, and/or for alleviating discomfort of lens wear and improving lens tolerance by physical means.

This standard provides test methodology to be used in developing performance specifications of CLCP by function and where appropriate provides acceptable performance specifications for specific products. It also addresses general requirements for CLCP based upon physical state of the marketed product (solutions, granules, and tablets), the packaging configuration (including conventional plastic container, aerosol container, form-fill-seal, or blister pack), and mode of use (unit dose or multi-dose).

2 References

The following standards contain provisions which, 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 standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid standards.

2.1 Normative References

ANSI Z80.20-2016, *Ophthalmics – Contact Lenses – Standard Terminology, Tolerances, Measurements and Physicochemical Properties*

ANSI/AAMI/ISO TIR 11139, *Sterilization of health care products – Vocabulary*

ANSI/AAMI/ISO 11607-1, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems, and packaging systems*

ANSI/AAMI ST67, *Sterilization of health care products – Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile"*

ISO 17665-1, *Sterilization of health care products – Moist heat – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices*

ISO 11135-1, *Sterilization of health care products – Ethylene oxide requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*