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Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11981:2009), which has been revised for clarity and to update all normative references.

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Ophthalmic optics — Contact lenses and contact lens care products — Determination of physical compatibility of contact lens care products with contact lenses

1 Scope

This document describes the general procedure and performance criteria for assessing the physical compatibility of contact lens care products with contact lenses and for determining whether the observed changes are reversible.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18369-1:2017, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

ISO 18369-2, *Ophthalmic optics — Contact lenses — Part 2: Tolerances*

ISO 18369-3:2017, *Ophthalmic optics — Contact lenses — Part 3: Measurement methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
cycle
sequence of events, following instructions for use or recommendations by the manufacturer of the contact lens care product, to occur between the time the contact lens is removed from the eye and before it is placed back into the eye

3.2
standard saline solution
specific phosphate buffered saline at a pH of 7,4 ± 0,1 and a nominal osmolarity of 310 ± 5 mOsm

Note 1 to entry: The provisions for formulation and preparation of standard saline solution are given in ISO 18369-3:2017, 4.9.

3.3
control solution
standard saline solution or appropriate justified alternative solution used to cycle contact lenses

Note 1 to entry: Control solutions are not required to comply with this document, but can be used to gain further information about the test.

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