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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 45808-2025

**Ophthalmic optics - Contact lenses and contact lens care
products - Cytotoxicity testing of contact lenses in combination
with lens care solution to evaluate lens/solution interactions**

眼科光学 接触镜和接触镜护理产品 基于接触镜结合接触镜护理液评价其相互作用
的细胞毒性试验

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is equivalent to ISO 18189:2016 "Ophthalmic optics contact lenses and contact lens care products based on contact lenses combined with contact lenses" Cytotoxicity test of nursing solutions to evaluate their interactions. The following minimal editorial changes were made to this document.

--- For the convenience of users of this document, "Cell Bank of the Chinese Academy of Sciences" has been added (see 5.2.2.1).

1 Scope

This document describes an in vitro test for evaluating the potential cytotoxic effects of interactions between contact lenses and contact lens care solutions. Test method.

This document applies to contact lenses and contact lens care solution products.

NOTE: The potential cytotoxicity caused by contact lenses or contact lens care solutions themselves is evaluated in accordance with ISO 10993-5.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

ISO 18369-1 Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommended labelling practices specifications)

Note: GB/T 11417.1-2012 Ophthalmic optics Contact lenses Part 1: Vocabulary, classification and recommended labeling specifications (ISO 18369-1:2006, MOD)

3 Terms and definitions

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

3.1 Room temperature

Defined as 18°C~25°C.

4 Principle

Chemicals in contact lens solutions may cause cytotoxic reactions in ocular tissues either directly or indirectly through contact lenses.

Absorption of preservatives or other solution components of contact lenses and subsequent release of these chemicals into the ocular environment may Potential interactions between contact lens care products and various contact lens materials should be considered when designing studies.

To comprehensively evaluate the cytotoxic potential of a new or modified contact lens material or contact lens care product.

5.1 General

The following protocol describes a test method for evaluating the potential cytotoxicity of contact lenses immersed in contact lens care solutions.