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

GB/T 28538-2023

Replacing GB/T 28538-2012

**Ophthalmic optics - Contact lenses and contact lenses care
products - Determination of biocompatibility by ocular study
with rabbit eyes**

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1. Structure and Drafting Rules of Standardization Documents"

Drafting.

GB (T)11417 "Ophthalmic Optical Contact Lenses", GB/T 28538 "Ophthalmic Optical Contact Lenses and Contact Lens Care Products Rabbit Eye Phase"

Capacitance Research Test" and GB/T 28539 "Determination Instructions for Intake and Release of Preservatives in Ophthalmic Optical Contact Lenses and Contact Lens Care Products

"South" together constitute a series of national standards for contact lenses.

This document replaces GB/T 28538-2012 "Study on Rabbit Eye Compatibility of Ophthalmic Optical Contact Lenses and Contact Lens Care Products"

"Experience", compared with GB/T 28538-2012, in addition to structural adjustments and editorial changes, the main technical changes are as follows.

---Added "Terms and Definitions" (see Chapter 3);

- Changed the "overall requirements" (see Chapter 4, Chapter 3 of the.2012 edition);
- Changed "Experimental Animals and Feeding and Management" (see Chapter 5, Chapter 4 of the.2012 edition);
- Changed "Preparation and Storage" (see 8.2, 7.2 of the.2012 version);
- Changed the "test procedures" (see Chapter 9, Chapter 8 of the.2012 edition);
- Changed the "Test Report" (see Chapter 11, Chapter 10 of the.2012 edition);
- Changed the "McDonald-Shadduck Scoring System---Slit Lamp" (see Appendix A, Appendix A of the.2012 version).

This document has been modified to adopt ISO 9394.2012 "Study and Test on Rabbit Eye Compatibility of Ophthalmic Optical Contact Lenses and Contact Lens Care Products".

The technical differences between this document and ISO 9394.2012 and their reasons are as follows.

- Deleted the normative references of ISO 18369-1 and OECD1997, and added the normative references of GB/T 11417.1 (see Section 3 Chapter) to adapt to my country's technical conditions;
- Replaced ISO 10993-1 (see Chapter 4) with the normatively cited GB/T 16886.1 to adapt to my country's technical conditions;
- Replaced ISO 10993-10 (see Chapter 4) with normatively quoted GB/T 16886.10 to adapt to my country's technical conditions;
- Replaced ISO /IEC 17025 (see Chapter 4) with normatively quoted GB/T 27025 to adapt to my country's technical conditions;
- Replaced ISO 10993-2 (see 5.2) with normatively quoted GB/T 16886.2 to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

- References changed.

Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents.

1 Scope

This document describes in vivo testing methods for evaluating the intraocular safety of contact lenses and contact lens care products. This test is to evaluate the product under test

The degree of irritation to eye tissue under experimental conditions.

This document applies to the rabbit eye test.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations

For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to

this document.

GB/T 11417.1 Ophthalmic optical contact lenses Part 1.Vocabulary, classification and recommended labeling specifications (GB/T 11417.1-

2012,ISO 18369-1.2006,MOD)

GB/T 16886.1 Biological evaluation of medical devices Part 1.Evaluation and testing during risk management process (GB/T 16886.1-

2022,ISO 10993-1.2018,IDT)

GB/T 16886.2 Biological evaluation of medical devices Part 2.Animal welfare requirements (GB/T 16886.2-2011, ISO 10993-

2.2006,IDT)

GB/T 16886.10 Biological evaluation of medical devices Part 10.Irritation and skin sensitization test (GB/T 16886.10-

2017,ISO 10993-10.2010,IDT)

GB/T 27025 General requirements for testing and calibration laboratory capabilities (GB/T 27025-2019, ISO /IEC 17025.2017,

IDT)

3 Terms and definitions

The terms and definitions defined in GB/T 11417.1 apply to this document.

4 General requirements

For biological evaluation and classification of medical devices in accordance with GB/T 16886.1, tests should be conducted in accordance with the requirements of GB/T 27025.

Irritation tests and sensitization tests for contact lenses and contact lens care products should be conducted in accordance with GB/T 16886.10.

Evaluation of results should be performed by experienced professionals.

5 Experimental animals and feeding and management

5.1 New Zealand albino rabbits (either male or female) or equivalent albino rabbits should be used for testing of each type of contact lens or contact lens care product.

test. Adult healthy rabbits from the same source and strain should be used, weighing more than 2.5kg. Rabbit eyes should have no obvious eye irritation or corneal fluorescein

clinical symptoms such as staining.