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

GB 11417.3-2025

Replacing GB 11417.3-2012

Ophthalmic optics - Contact lenses - Part 3: Soft contact lenses

眼科光学 接触镜 第3部分：软性接触镜

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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 Contact Lenses" and GB/T 28538 "Ophthalmic Contact Lenses and Contact Lens Care Products - Rabbiteye Diagnosis" The standards include "Cost Compatibility Study Test" and GB/T 28539 "Determination of Preservative Intake and Release in Ophthalmic Optical Contact Lenses and Contact Lens Care Products". This constitutes a series of national standards for contact lenses. This document is Part 3 of GB (T) 11417 "Ophthalmic Optics Contact Lenses". GB (T) 11417 has already published the following parts.

- 1. Identification Guidelines for Vocabulary, Classification, and Recommendations;
- 2. Rigid Contact Lenses;
- 3. Soft Contact Lenses;
- 4. Standard salt solutions for testing;
- 5. Test methods for optical properties;
- 6. Test methods for mechanical properties;
- 7. Test methods for physical and chemical properties;

8.Determination of Validity Period;

9.Ultraviolet and Visible Radiation Aging Tests (In Vitro Method) This document supersedes GB 11417.3-2012 "Ophthalmic Optics Contact Lenses Part

3.Soft Contact Lenses", and is consistent with GB 11417.3- Compared to.2012, aside from structural adjustments and editorial changes, the main technical changes are as follows:

---The scope has been changed (see Chapter 1, Chapter 1 of the.2012 edition);

---Terminology and definitions have been revised (see Chapter 3, Chapter 3 of the.2012 edition);

1 Scope

Part 3 of China's mandatory national standard for contact lenses, covering soft lenses. A soft lens is a hydrogel - a water-swollen polymer that drapes onto the cornea and takes its shape, which is what makes it comfortable within minutes where a rigid lens takes weeks of adaptation, and why it holds the great majority of the market. Its properties follow from its water content and are all connected: more water means more oxygen reaches the cornea but a weaker, more fragile lens that dehydrates during the day. Silicone hydrogels broke that link and are why extended wear became possible. The requirements cover the dimensions and power in the hydrated state, since a soft lens measured dry is meaningless, the oxygen transmissibility, the mechanical properties, and the biological safety of a device worn against the eye for hours a day. This part specifies the requirements and test methods for soft contact lenses.

This document specifies the requirements, labeling, marking, and accompanying documentation for soft contact lenses, and describes the test methods. This document applies to soft contact lenses.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 11417.1 Ophthalmic contact lenses - Part

3 Terms and Definitions

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

4.1 General Requirements In addition to the requirements in

4.2 to 4.8, if the manufacturer expressly indicates any other special designs or additional performance features, a detailed description shall be provided, along with applicable requirements. Summation test method.

4.2 Optical Performance

4.2.1 General Rules For contact lenses intended for special medical purposes and lacking optical properties, if clearly described in the accompanying documentation and labeling,

4.2.4 Optical performance requirements may not apply.

5 Test Methods for Optical Performance

GB/T 11417.6 Ophthalmic Contact Lenses - Part

6 Test Methods for Mechanical Properties

GB/T 11417.7 Ophthalmic optical contact lenses - Part

7 Test methods for physical and chemical properties

GB/T 11417.8 Ophthalmic Contact Lenses - Part

8 Determination of Shelf Life

GB/T 11417.9 Ophthalmic contact lenses - Part

9 Ultraviolet and visible light radiation aging test (in vitro method)

GB/T 16886.1 Biological evaluation of medical devices - Part