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

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Replacing GB 11417.2-2012

**Ophthalmic optics - Contact lenses - Part 2: Rigid contact
lenses**

眼科光学 接触镜 第2部分：硬性接触镜

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Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Requirements
- 4.2 Optical properties
- 5 Testing methods for optical properties
- 6 Mechanical properties test methods
- 7 Physicochemical properties test methods
- 8 Determination of shelf- life
- 9 Ageing by exposure to UV and visible radiation (in vitro method)
- 17 References...

Foreword

GB(T) 11417 Ophthalmic optics - Contact lenses is divided into the following parts. -- Part

1.Vocabulary, classification and recommendations for labelling specifications. The purpose is to define the terms and definitions for contact lenses. -- Part

2.Rigid contact lenses. The purpose is to specify the performance requirements for rigid contact lenses. -- Part

3.Soft contact lenses. The purpose is to specify the performance requirements for soft contact lenses. -- Part

4.Saline solution for contact lens testing. The purpose is to specify the requirements for standard saline solutions used in contact lens testing. -- Part

5.Testing methods for optical properties. The purpose is to specify the test methods for the optical properties of contact lenses. -- Part

6.Mechanical properties test methods. The purpose is to specify the test methods for the mechanical properties of contact lenses. -- Part

7.Physicochemical properties test methods. The purpose is to specify the test methods for the physical and chemical properties of contact lens materials. -- Part

8.Determination of shelf-life. The purpose is to specify the testing procedures for the stability of contact lenses during storage. -- Part

9. Ageing by exposure to UV and visible radiation (in vitro method). The purpose is to specify the in vitro test method for aging contact lenses under simulated sunlight irradiation. This document and GB 11417.3 are the core product standards in the field of contact lenses, and other related standards revolve around and serve these two core standards. Although relevant contact lens standards exist internationally, their framework and requirements have not yet formed a systematic standard system. This document references ISO 14534, ISO 18369, and ANSI Z80.20. During the revision process, the key clauses of the standards underwent thorough research and technical verification, striving to ensure that the revised standards can more effectively support market supervision, guide the high-quality development of the industry, promote technological progress, and protect public safety in the use of medical devices. Ophthalmic optics - Contact lenses - Part

1 Scope

Part 2 of China's mandatory national standard for contact lenses, covering rigid lenses. A rigid gas-permeable lens is a small piece of precisely figured polymer that floats on the tear film and does not follow the shape of the cornea - which is exactly why it is prescribed: it replaces the corneal surface with its own optical surface, and so corrects astigmatism and keratoconus that no soft lens can. Its performance depends on properties that must be specified and verified: the back optic zone radius that determines how it fits, the total diameter and edge form that decide whether it is tolerable to wear, the optical power and its tolerance, and above all the oxygen permeability, since the cornea has no blood supply and takes its oxygen from the air through the tear film. A lens too impermeable produces corneal oedema. This part specifies the requirements and test methods for rigid lenses.

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

2 Normative references

The provisions of the following documents constitute the essential clauses of this document through normative references in this text. Among them, for any dated reference, only the version corresponding to that date applies to this document; for any undated reference, the latest version (including all amendments) applies to this document.

GB/T 11417.1 Ophthalmic optics - Contact lenses - Part

3 Terms and definitions

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

4 Requirements

4.1 General requirements In addition to the requirements in 4.2~4.8, if the manufacturer expressly indicates any other special design or additional performance, a detailed description shall be provided, along with applicable requirements and test methods.

4.2 Optical properties

4.2.1 General rules For contact lenses intended for special medical purposes and lacking optical properties, the optical property requirements in 4.2.2~

4.2.4 may not apply if they are clearly described in the accompanying documents and markings.

4.2.2 Back vertex power, cylinder power, and cylinder axis The nominal values of the back vertex power, cylinder power, and cylinder axis (if any) of the contact lens shall be marked on the small packaging container, and the tolerance of the nominal values shall comply with the provisions of Table 1. for its light transmittance performance, a detailed description shall be given in the accompanying documents, along with the applicable requirements and test methods.

4.2.4.2 Visible light requirements The visible light transmittance and color vision of contact lenses shall meet the following requirements.

a) The luminous transmittance τ_V under standard illuminators D65 and A is not less than 85%.

b) For tinted contact lenses, analyze and evaluate whether color vision after wearing the lenses meets the requirements for daily use. The analysis and evaluation of the impact on color vision can be performed using the spectrums of an illuminator conforming to Planck's Blackbody radiation law and the International Commission on Illumination (CIE) illuminator D, analyzing the reduction in color rendering index after passing through the contact lens, and combining this with practical application. The correlated color temperature of the illuminator shall be selected to characterize practical application; at least three illuminators with high, medium, and low color temperatures shall be selected, and the selected illuminators and their correlated color temperatures shall be recorded. NOTE

1. The illuminators selected in the analysis of influence on color vision are the standard illuminators A, D50 and D75 specified in GB/T 3978. NOTE

2. The color rendering index is calculated according to the evaluation method for the color rendering of light sources specified in GB/T 5702. If the manufacturer explicitly states that tinted contact lenses or contact lenses with special functions have a specific application purpose and are not applicable to visible light transmittance and/or color vision requirements, the safety and effectiveness of the visual acuity and/or color vision after wearing the lenses in the application shall be evaluated.

5 Testing methods for optical properties

GB/T 11417.6 Ophthalmic optics - Contact lenses - Part

6 Mechanical properties test methods

GB/T 11417.7 Ophthalmic optics - Contact lenses - Part

7 Physicochemical properties test methods

GB/T 11417.8 Ophthalmic optics - Contact lenses - Part

8 Determination of shelf- life

GB/T 11417.9 Ophthalmic optics - Contact lenses - Part

9 Ageing by exposure to UV and visible radiation (in vitro method)

GB/T 16886.1 Biological evaluation of medical devices - Part