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REPUBLIC OF CHINA

中华人民共和国医药行业标准

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Rigid gas permeable contact lenses for orthokeratology

角膜塑形用硬性透气接触镜

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Foreword

The standard is not the equivalent international standards, which is established in comparison with the technical content in the relevant international and domestic standards and the relevant content of the foreign and domestic law and regulations, mainly including:

ISO 8320-1 Ophthalmic Optics -- Vocabulary of Contact Lenses and Care Products -- Basic Requirements

ISO 8321-1 Optics and Optic Instruments -- Contact Lenses -- Part 1: Rigid Gas Permeable Contact Lens

ISO 8599 Ophthalmic Optics -- Contact Lenses -- Spectral Transmittance Test

ISO 9337-1 Ophthalmic Optics -- Contact Lenses -- Back Vertex Dioptric Test -- Part 1: Lensometer

ISO 9338 Ophthalmic Optics -- Contact Lenses -- Diameter Measurement

ISO 9339-1 Ophthalmic Optics -- Contact Lenses -- Thickness Measurement -- Part 1: Rigid Contact Lenses

ISO 9340 Ophthalmic Optics -- Contact Lenses -- Stress Test of Rigid Contact Lenses

ISO 9341 Ophthalmic Optics -- Contact Lenses -- Tests for Inherent Quality and Surface Defect of Rigid Contact Lenses

ISO 9363-1 Ophthalmic Optics -- Contact Lenses -- Biological Compatibility of Contact Lenses -- Evaluation on Cytotoxicity Test -- Part 1: Agar Overlay Test and Growth Inhibition Test

ISO 9394 Ophthalmic Optics -- Evaluation on Material Biocompatibility of Contact Lenses -- Test of Contact Lenses in Rabbits' Eyes

ISO 9913-1 Ophthalmic Optics -- Contact Lenses -- Polarographic Oxygen Permeability Measurement

ISO 9913-2 Ophthalmic Optics -- Contact Lenses -- Measurement of Oxygen Permeability through Coulomb

ISO 9914 Ophthalmic Optics - Contact Lenses - Measurements for Refractive Index -- Materials -- Contact Lenses

ISO 10338 Ophthalmic Optics -- Contact Lenses -- Curvature Measurement

ISO 10334 Ophthalmic Optics -- Contact Lenses -- Salt Solution Used in the Test of Contact Lenses

ISO 10340 Ophthalmic Optics -- Contact Lenses -- Methods for Measurement of Extractable Materials

ISO 11539 Ophthalmic Optics -- Contact Lenses -- Methods for the Classification of Care Products for Contact Lenses and Corneal Contact Lenses

ISO 14534 Ophthalmic Optics -- Vocabulary of Contact Lenses and Care Products -- Basic Requirements

Administrative regulations of the Provisions on the Supervision and Administration of Orthokeratology

Operation issued by the State Food and Drug Administration.

Technical document of the Listing Guide for Rigid Gas Permeable Contact Lenses for Orthokeratology issued by the U.S. FDA.

The standard related to the technical and safety performance of medical devices and products, belonging to the mandatory standards.

Annex A and Annex B of the Standard are the normative annexes. At the same time, in consideration of the actual situation of rigid gas permeable contact lenses for orthokeratology in the implementation of orthokeratology, the quality of the rigid gas permeable contact lenses for orthokeratology is only one aspect of its efficacy and safety in clinical application, and correct fitting is another important aspect. For this reason, in Annex C of this standard, the recommended standardized fitting program is proposed as the informative annex of the standard.

The standard is proposed by the State Food and Drug Administration.

The standard is under the jurisdiction of the National Technical Committee on Optics & Optic Instruments of Standardization Administration of China.

The standard is drafted out by Hangzhou Medical Device Quality Supervision and Inspection Center of State Food and Drug Administration.

Main Drafters of this Standard: He Tao, Jia Xiaohang, Chen Xianhua, Jiang Xiaolu and Wen Yan.

Rigid Gas Permeable Contact Lenses for Orthokeratology

1 Scope

This standard specifies the classification, technical requirements, testing method, inspection rules, packing requirement and the recommended fitting program of the rigid gas permeable contact lenses for orthokeratology.

2 Normative References

The articles contained in the following documents have become this standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 14233.2 Test Methods for Infusion, Transfusion, Injection Equipments for Medical Use Part 2: Biological Test Methods

GB/T 17341 Optics and Optical Instruments Lensometer

GB/T 16886.5 Biological Evaluation of Medical Devices Part 5: Tests for in vitro Cytotoxicity

GB/T 16886.10 Biological Evaluation of Medical Devices Part 10: Eye Irritation and Sensitization Tests

GB/T 16886.11 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity

ISO 10334 Ophthalmic Optics -- Contact Lenses -- Salt Solution Used in the Test of Contact Lenses

Pharmacopeia of the People's Republic of China (2000 edition)

3 Terms and Definitions

For the purpose of this standard, the following terms and definitions apply.

3.1

Contact Lenses

Any lens designed to be worn on the front surface of the cornea.

Note: The definition of contact lenses includes the myopic lenses, hyperopia lenses and trial (diagnostic) lenses.

3.2

Rigid Gas Permeable Contact Lenses

Contact lenses made of rigid gas permeable material, usually the polymeric material used for contact lenses contains the organic silicone and organic fluorine components.

3.3

Rigid Gas Permeable Contact Lenses for Orthokeratology

The rigid gas permeable contact lenses for orthokeratology are a kind of the rigid gas permeable contact lenses (hereinafter referred to as orthokeratology contact lenses) that are used to correct the

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