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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 0718-2009

Ophthalmic instruments - Retinoscopes

眼科仪器 检影镜

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Foreword

This standard is equivalent to international standard ISO 12865.2006 "retinoscope ophthalmic instruments." For ease of use, this standard made the following editorial changes.

- a) "this International Standard" be replaced by "this standard";
- b) with a decimal point, instead of as a decimal comma " , " . " , " ;
- c) Remove the preface to international standards. This standard by the national medical and optical instruments Standardization Technical Committee and centralized. This standard was drafted. State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center. The main drafters of this standard. Wang Jingtao, JIA Xiao Hang Feng Qin. YY 0718-2009/ISO 12865.2006 Retinoscope ophthalmic instruments

1 Scope

YY 0718 is the mandatory Chinese standard for retinoscopes, the handheld instruments used to determine a refractive error objectively by observing the reflex from the retina. Retinoscopy is how a prescription is obtained in patients who cannot answer questions: infants, young children, people with intellectual disability or language barriers, and it remains a core skill in Chinese optometry and paediatric ophthalmology. This document sets the requirements such an instrument has to meet and the test methods that verify them, covering the illumination system and the streak or spot it projects, the optical quality of the viewing path, the mechanical construction and the light exposure limits that protect the eye under examination. Being a YY standard without the /T suffix, compliance is compulsory in China. It carries Amendment 1 of 2023.

The ISO 15004-1 standard and common provisions for objective measurement of the eye refractive errors ribbon optical retinoscope and point-like light retinoscopy mirror Minimum requirements and test methods. The ISO 15004-1 standard and if there is, the present standard in preference to ISO 15004-1.

2 Normative references

The following documents contain provisions which, through reference in this standard and become the standard terms. For dated references, subsequent Amendments (not including errata content) or revisions do not apply to this standard, however, encourage the parties to the agreement are based on research Whether the latest versions of these documents. For undated reference documents, the latest versions apply to this standard.

GB 9706.1-2007 Medical electrical equipment - Part 1. General requirements for safety (IEC 60601-1. 1988, IDT)

ISO 15004-1 ophthalmic instruments General requirements and test methods

3 Terms and Definitions

The following terms and definitions apply to this standard.

3.1 Objective assessment of the refractive error eye and retinal reflection cross over the pupil when the displacement of ophthalmic instruments by specular reflection beam. NOTE. retinoscope typically include analysis by the center through light microscopy or optical mirror projection system, observation system and power supply.

3.2 Can produce a focal length and orientation of the adjustable rectangular cross-section beam retinoscope.

3.3 Capable of generating a bundle of approximately circular cross-section beam retinoscope. NOTE. Focus image can be adjusted.

4 Requirements

4.1 General requirements Retinoscope should meet the general requirements specified in ISO 15004-1. Retinoscope shall comply with the requirements of

4.2 to 4.3. These requirements should be verified in accordance with the provisions of Chapter 5.

4.2 Optical and mechanical requirements Retinoscope shall comply with the requirements of Table 1. YY 0718-2009/ISO 12865.2006