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

YY 0674-2008

Ophthalmic instruments - Phoropters

眼科仪器 验光头

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Foreword

This revised standard adopts the International Standard ISO 10341.1997 "ophthalmic instruments optometry head." This standard and ISO 10341.1997 The main differences are as follows:

a) This standard ISO 15004.1997 standard

4.4 material requirements, modifications incorporated this standard

4.4 requirements;

b) This standard ISO 15004.1997 standard 4.5, adding a reference to the present requirements of the standard 4.5;

c) Environmental requirements and test methods for the use of the relevant provisions of GB/T 14710-1993 of;

d) require the use of safety requirements GB 9706.1. This standard is based on ISO 10341.1998 redrafting changes, modifications and technical differences made have been incorporated into the text in which they are involved Logo | Terms margin of a single vertical line (). Appendix A of this standard is an informative annex. This standard by the National Standardization Technical Committee of medical and optical instruments and optical instruments at the Technical Committee (SAC/TC103/SC1) and focal points. This standard was drafted. State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center. Drafters of this standard. Wen Yan, JIA Xiao Hang, Wang Jingtao, He Tao, Qi Weiming, Mary. Ophthalmic instruments optometry head

1 Scope

YY 0674 is the mandatory Chinese standard for phoropters, the instrument of stacked lenses through which a patient reads a chart while the optometrist changes the correction to find the prescription. It sets the requirements such an instrument has to meet and the test methods that verify them, covering the power and accuracy of the spherical and cylindrical lenses, the accuracy of the cylinder axis, the prism, the interpupillary adjustment and the mechanical operation of the wheels. An error in the phoropter propagates into

every prescription written with it, and the patient wears it. Refraction volumes in China are enormous, driven by the prevalence of myopia in the school-age population. Compliance is compulsory in China.

This standard gives requirements and test methods for measuring the human eye binocular vision and refractive errors optometry head.

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

GB/T 10050-1988 and optical equipment reference wavelength (eqv ISO 7944. 1984)

GB/T 14710-1993 Medical electrical equipment environmental requirements and test methods

GB/T 16886.5-2003 Biological evaluation of medical devices - Part 5. In vitro cytotoxicity tests (ISO 10993-5.1999, IDT)

GB/T 16886.10-2005 Biological evaluation of medical devices - Part 10. irritation and delayed-type hypersensitivity test (ISO 10993-10.2002, IDT)

ISO 8429. 1986 Optics and optical instruments - Ophthalmology dial

ISO 15004.1997 ophthalmic instruments basic requirements and test methods

3 Terms and Definitions

The following terms and definitions apply to this standard.

3.1 To provide spherical lenses, cylinder lenses and a prism sheet and other optics equipment can be placed in front of people measure the patient's binocular vision and Qu Light errors.

3.2 Head for measuring the refraction power of tolerance of positioning plane.

3.3 Optometry head reference plane and the distance between the corneal vertex.

3.4 The intersection of the optical axis of the lens on the lens surface.

3.5 Lenses and optical surfaces by changing the curvature or refraction through the ability to change the direction of the incident surface.