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

YY 0792.2-2010

**Ophthalmic instruments - Endoilluminators - Part 2:
Fundamental requirements and test methods for optical
radiation safety**

眼科仪器 眼内照明器 第2部分：光辐射安全的基本要求和试验方法

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Table of Contents

- 1 Scope
- 2 Normative reference documents
- 3 Terms and definitions

Foreword

YY 0792 "ophthalmic instrument eye illumination device" is divided into two parts. - Part 1. General requirements; - Part 2. Basic requirements and test methods for the safety of optical radiation; This part is part 2 of YY 0792. This part of the revised use of ISO 15752..2000 "ophthalmic instruments, intraocular lighting, optical radiation safety of the basic requirements and test methods" (English version). The main differences between this part and ISO 15752..2000 are as follows:

a) IEC 60601-1..1998 and IEC 60601-1 appearing in ISO 15752..2000 to correspond to our national standard GB 9706.1-2007 and GB 9706.1. b)

3.1.1 Terminology. "Effective pore size" is supplemented by the same term as the "light aperture", which complements the equivalent pore size method.

c) an increase of the

4.3.3 setpoint deviation clause; d)

4.5.1 supplemented the limitation of the provisions of the increase in the form of instructions and additional instructions. This part is redrafted in accordance with ISO 15752..2000, and the modifications and technical differences have been incorporated into the text and in which they are The blanks of the terms are marked with a vertical single line (|). Appendix A and Appendix B of this section are normative and Appendix C is an informative appendix. This part is proposed and assigned by the National Standardization Subcommittee for Medical Optics and Instruments (SAC/TC103/SC1). This part of the drafting unit. the State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center. This part of the main drafters. Jia Xiaohang, Wen Yan, Wang Jingtao. Ophthalmic instruments intraocular luminaire Part 2. basic requirements for the safety of optical radiation and experiment method

1 Scope

YY 0792.2 covers the optical radiation safety of endoilluminators, the fibre light probes inserted into the eye during vitreoretinal surgery. The probe illuminates the retina from a few millimetres away, for the length of an operation, in an eye whose protective reflexes are

absent, which makes retinal phototoxicity a real and documented complication of long vitrectomies. This part sets the fundamental requirements and test methods for that safety, covering the spectral output, the retinal irradiance the probe produces and the maximum exposure durations the manufacturer has to state. Vitreoretinal surgery volumes are large and growing in China with the burden of diabetic eye disease. Being a YY standard without the /T suffix, compliance is compulsory.

This part of YY 0792 specifies the optical radiation safety requirements for intraocular lasers. The intraocular illuminator is used for eye surgery during ophthalmic surgery Ming use. This section does not apply to other active and passive ophthalmic devices and surgical microscopes.

2 Normative reference documents

The terms of this document are incorporated by reference in this section and become part of this section. Whichever is the date of the reference file, which is followed by all (Excluding corrigenda) or revisions do not apply to this part, however, encourage parties to reach an agreement under this section Whether you can use the latest version of these files. For undated references, the latest edition applies to this section.

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

3 Terms and definitions

The following terms and definitions apply to this part of YY 0792.

3.1 Aperture Usually a circular through-hole through which light can enter an optical system.

3.1.1 Effective aperture effectiveaperture Through aperture Limiting the aperture of the amount of light projected onto the ocular retina.

Note. For non-intangible and non-circular through-aperture, equivalent to the straight-through circular aperture treatment; for porous perforated aperture, according to the area of the equivalent of the circle Shaped aperture treatment.

3.1.2 Numerical aperture The numerical aperture of the fiber is represented by the product of the refractive index of the medium in which the object is illuminated and the sinusoidal sinusoidal value of the illumination cone. $NA = n' \sin u'$ Where. n'

--- the refractive index of the medium in which the object is illuminated; u'

--- half of the light cone angle.

3.1.3 The aperture is exitingaperture The light guide portion of the intraocular illuminator, the light emitted by the intraocular illuminator light source, is output through the light guide.

3.2 Intraocular illuminator endoiluminator A device consisting of an intraocular illuminator light source and an optical fiber synthetic intraocular illuminator light guide is intended to be inserted into the eye for eye

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