ICS 11.040.70

C 40

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

中华人民共和国国家标准

GB 11417.2-2012

Replace GB 11417.1-1989

Ophthalmic optics-Contact lenses—Part 2: Rigid contact lenses specification

眼科光学 接触镜

第 2 部分：硬性接触镜

Issued on December 31, 2012 Implemented on December 1, 2013

Issued by General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Committee of Standardization Administration of the People's Republic of China

Contents

Foreword

This Section 4.3.3.2 and 4.7.1 are recommendatory. The rest is mandatory.

Ophthalmic Optics-Contact Lenses, GB/T28539 *Ophthalmic Optics-Contact Lenses and Contact Lens Care Products- Guidelines for Determination of Preservative Uptake and Release* and GB/T28538 *Ophthalmic Optics-Contact Lenses and Contact Lens Care Products- Determination of Biocompatibility by Ocular Study with Rabbit Eyes* jointly constitute the national standards of contact lenses.

There are nine divided Parts in *Ophthalmic Optics*:

—— Part 1: *Vocabulary, Classification System and Recommendations for Labeling Specifications* (GB/T 11417.1)

—— Part 2: *Rigid contact lenses*; (GB 11417.2)

—— Part 3: *Soft contact lenses*; (GB 11417.3)

—— Part 4: *Standard salt solution for test*; (GB/T 11417.4)

—— Part 5: *Test methods for optical properties*; (GB/T 11417.5)

—— Part 6: *Mechanical properties test methods*; (GB/T 11417.6)

—— Part 7: *Physicochemical properties test methods* (GB/T 11417.7)

—— Part 8: *Determination of shelf-life*; (GB/T 11417.8)

—— Part 9: *Ageing by exposure to UV and visible radiation* (in vitro method) (GB/T 11417.9)

This Part is Part 2.

This part is drafted according to the rules specified in GB/T 1.1-2009.

This Part replaces GB 11417.1-1989 *Rigid corneal contact lenses* and Amendment 1 in 1997.

Except editorial amendment, the technical content of this Part, GB 11417.1-1989 and Amendment 1 in 1997 are changed as follows:

—— Amended the requirements of biological compatibility, refractive index, optical deviation, geometric dimensioning, impurities, surface defects, fenestration, limbic shape, luminous transmittance, and spectral transmittance;

—— Modified the test methods (Chapter 6);

—— Modified the sampling and inspection rules (Chapter 7);

—— Modified the contents of signs (Chapter 8);

—— Deleted requirements for the stress and lens shape;

—— Deleted the wear requirements (Chapter 9);

—— Supplemented requirements of ultraviolet spectrum performance, amount of oxygen permeability, coefficient of oxygen permeability, mechanical property, physicochemical properties of materials, microorganism and stability.

This Part is redrafted and compiled by referring to ISO 14534:2002 *Ophthalmic Optics-Contact Lenses and Contact Lens Care Products-Fundamental Requirements*, ISO18369:2006 *Ophthalmic Optics-Contact Lenses*, and ANSI Z80.20 *Ophthalmic Optics-Contact Lenses-Terminology, Tolerances, Measurement Methods and Physicochemical Properties*.

Please note that some contents in this file may involve patents. The issued institution of this file shall not bear the responsibility to identify these patents.

This Part is proposed by the China Food and Drug Administration.

Responsible drafting organizations of this Part: Technical Subcommittee of Medical Optics and Instrument of National Optics and Photonics Technical Committee for Standardization (SAC/TC 103/SC1).

The drafted organization of the Part are: Participating drafting organizations of this Part: China Food and Drug Administration, Supervising and Testing Center of Hangzhou Zhejiang Institute for the control of Medical Device and Supervising and Testing Center of Hangzhou.

Main drafters of this Part: He Tao, Jia Xiaohang, Wen Yan, Ma Li, Jiang Xiaolu, Chen Xianhua, Zheng Jian, Qi Weiming, Li Jiazhong, Chen Jingyun.

The issuance condition of the standard previous versions replaced by the Part is:

—— GB 11417.1-1989 and Amendment 1 in 1997.

Ophthalmic optics-Contact lenses-

Part 2: Rigid contact lenses specification

1 Scope

This Part of GB 11417 specifies the scope, terminology, definition, requirements, test method, sampling, inspection regulations, label, mark, and attached documents of rigid contact lenses (hereinafter referred to as contact lenses).

This section applies to rigid cornea and scleral contact lenses.

2 Normative references

The articles contained in the following documents have become this document when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this document.

GB/T 2829-2002 Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of process stability)

GB/T 3978-2008 Standard illuminants and geometric conditions

GB/T 5702-2003 Methods of measuring the color of light sources

GB/T 11417.1-2012 Ophthalmic optics—Contact lenses—Part 1:Vocabulary, classification system and recommendations for labeling specifications

GB/T 16886.5 Biological evaluation of medical devices--Part 5: Test for in vitro cytotoxicity

GB/T 16886.10 Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity

GB/T 16886.11 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity

GB/T 19973.1 Sterilization of medical devices–Microbiological methods—Part 1: Estimation of population of microorganisms on products

YY/T 0297 Clinical investigation of medical devices

YY/T 0316 Medical devices—Application of risk management to medical devices

YY/T 0466.1 Medical devices—Symbols to be used with medical device labels,

北京文心雕语翻译有限公司
Beijing Lancarver Translation Inc.

完整版本请在线下单/Order Checks Online for Full version

联系我们/or Contact:

TEL: 400-678-1309

QQ: 19315219 | Skype: Lancarver

Email：info@lancarver.com

http://www.lancarver.com

线下付款方式：

I. 对公账户：

单位名称：北京文心雕语翻译有限公司

开 户 行：中国工商银行北京学清路支行

账　　号：0200 1486 0900 0006 131

II. 支付宝账户：info@lancarver.com

III. Paypal: info@lancarver.com

注: 付款成功后，请预留电邮，完整版本将在一个工作日内通过电子 PDF 或 Word 形式发送至您的预留邮箱，如需索取发票，下单成功后的三个工作日内安排开具并寄出，预祝合作愉快！

NOTE All documents on the store are in electronic Adobe Acrobat PDF format, there is not sell or ship documents in hard copy. Mail the order and payment information to info@lancarver.com , you will shortly receive an e-mail confirming your order.