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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB 14724-2009

Replacing GB 14724-1993

Hard ocular prosthesis

硬质假眼

(English Translation)

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Foreword

The standard Chapter 5, Chapter 6 and Chapter 7 are mandatory, the remaining chapters are recommended.

This standard replaces GB 14724-1993 "Hard false eye." this standard compared with GB 14724-1993 main changes are as follows.

- a) Normative references, using GB/T 2828.1 "Sampling procedures for inspection - Part 1. by acceptance quality limit (AQL) inspection CABLE batch inspection sampling plan ", YY0270" dentistry denture base polymer ", YY/T 0268" Dentistry for oral Biocompatibility preclinical evaluation of medical devices cavity Module 1. Evaluation and testing project selection "and GB/T 16432" disability Classification and terminology aids people "instead of GB 2828" batch inspection Sampling procedures and sample forms (for continuous batch Check) ", GB 1710" pigment lightfastness Determination ", GB 8265" synthetic resin teeth "and GB 11417.1" hard corneal contact Contact lens ";
- b) terms, modified thin artificial eye, artificial eye-shaped thick and special fake eye definitions of terms described increased Implantation Term Name Definition;
- c) product category, product type and meaning an increase of the left and right to mark the location, design sequence number is deleted;
- d) according to YY0270 "dentistry denture base polymer" requirements, and test methods for color stabilization has been modified;
- e) in accordance with GB 11417.1 "hard contact lenses" Edit No. single request, removed the technical requirements of fake eye tensile strength;
- f) in accordance with YY/T 0268 "Dentistry for preclinical evaluation of biocompatibility of medical devices oral first unit. Evaluation Select the pilot project "requirements, test methods for safety and health requirements have been modified;
- g) prepared pursuant to the rules of product standards, remove the requirement to wear.

The standard proposed by the People's Republic of China Ministry of Civil Affairs.

This standard by the national rehabilitation and special equipment Standardization Technical Committee on Persons with Disabilities (SAC/TC148) centralized.

This standard was drafted. prosthetic Shanghai Co., Ltd., Shanghai China Technology Co., Ltd. Pok Hong multiplexing apparatus, the State Quality Supervision and rehabilitation equipment Inspection Center, Beijing orthopedic technology center in Sichuan physically disabled rehabilitation center.

1 Scope

This standard specifies the hard artificial eye terms, product classifications, technical requirements, test methods, inspection rules and signs, packaging, transportation and storage.

This standard applies to rigid polymer material false eye (hereinafter referred to as false

eye).

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/T 191 Packaging - Pictorial signs (GB/T 191-2000, eqv ISO 780:1997) GB/T 2828.1 Sampling procedures for inspection - Part 1. by acceptance quality limit (AQL) retrieval batch inspection sampling plan (GB/T 2828.1-2003, ISO 2859-1:1999, IDT) GB/T 16432 Classification and terminology aids for disabled persons (GB/T 16432-2004, ISO 9999:2002, IDT) YY/T 0268 Dentistry Oral Biological evaluation of medical devices Module 1. Evaluation and testing (YY/T 0268-2008, neq ISO/FDIS7405.2008) YY0270-2003 dentistry denture base polymers (ISO 1567:1999, MOD)

3 Terms and Definitions

The following terms and definitions apply to this standard.

Imitation external appearance of the eye tissue prosthesis.

For enucleation, evisceration and post-atrophic eyeball cavity filled eyes, make up the artificial eye eye defects.

Note: references GB/T 16432063021 3.2 with a hard material, not deformed when wearing fake eye.

The equivalent of the cornea and the iris portion of the human eye.

Part of the body is equivalent to the sclera of the eye.

Equivalent to the human eye's pupil.

The human equivalent of the eye capillaries, red fibers arranged on the surface of the whites.

Press fake eye normal assembly position, the maximum size of the frontal plane in the horizontal direction.

Press fake eye normal assembly position, the maximum size of the frontal plane in the vertical direction.

It refers to the eye after enucleation or evisceration, or two while the ocular implantation muscle cone or sclera cavity to replace the missing eyes Volume, correct orbital depression.

3.10

Adaptation has been in the eye atrophy or ocular implantation in patients wearing fake eye.

3.11

Adaptation enucleation or evisceration patients wearing fake eye.

3.12

Adaptation has been in orbital implant implantation and drilling peg patient wearing fake eye.

4.1 Varieties

Ocular prosthesis according to the thickness is divided into.

- a) thin artificial eye, Pinyin letters "B" represents;
- b) thick false eye shape, Pinyin letters "H" represents;
- c) special fake eye, Pinyin letters "T" represents.

4.2 Specifications

Making false eye generally varies customization. When mass production, its size specifications are shown in Table 1.

Table 1 millimeters

Specifications	major axis diameter	minor axis diameter	black eye no. 1	no. 2	no. 3
20 to 23	23 to 26	26 to 30	17 to 20	20 to 22	22 ~ 25
9.5-10.5	10.5 to 11.5	11.5-12.5			

4.3 Model and meaning

false eye code

species classification code Main parameters (long axis x short axis), mm Lateral position (on the left -L, right side -R) Model example.

On the left, the long axis of 24mm, 19mm short axis of thin fake eye; expressed as JYB-24 x 19L.

4.4 Structure icon

Structure shown in Figure 1.

Figure 1