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

YY/T 0787-2024

Replacing YY/T 0787-2010

Ophthalmic instruments - Corneal topographers

眼科仪器 角膜地形图仪

(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document replaces YY/T 0787-2010 "Ophthalmic Instruments Corneal Topography", and compared with YY/T 0787-2010, except for the structural adjustment in addition to the integration and editorial changes, the main technical changes are as follows.

- Deleted the term and definition of "corneal semi-meridian" (see 3.3.1 of the 2010 edition);
- Deleted the term and definition of "corneal curvature constant" (see 3.11 of the 2010 edition);
- Deleted the term and definition of "meridian plane" (see 3.13 of the 2010 edition);
- Deleted the term and definition of "p value" (see 3.15 of the 2010 edition);
- Deleted the terms and definitions of "Placido ring mark" (see 3.16 of the 2010 edition);
- Deleted the term and definition of "aspherical surface" (see 3.18.1 of the 2010 edition);
- Deleted the term and definition of "non-annular surface" (see 3.18.2 of the 2010 edition);

- Deleted the term and definition of "oblate noodles" (see 3.18.3 of the 2010 edition);
- Deleted the term and definition of "long oval surface" (see 3.18.4 of the 2010 edition);
- Deleted the term and definition of "cross section" (see 3.20 of the 2010 edition);
- Added the term and definition of "corneal refractive power" (see 3.11);
- Deleted the "material" requirements (see 4.5 of the 2010 edition);
- Deleted the "cleaning, disinfection or sterilization measures" requirement (see 4.6 of the 2010 edition);
- Deleted the "environmental conditions" requirement (see 4.7 of the 2010 edition);
- Changed the "Electrical safety" requirements (see 4.5, 4.8 of the 2010 edition);
- Added "electromagnetic compatibility" requirements (see 4.6);
- Deleted the "Material Test" test method (see 5.5 of the 2010 edition);
- Deleted the test method of "Cleaning, disinfection or sterilization measures inspection" (see 5.6 of the 2010 edition);
- Deleted the "Environmental test" test method (see 5.7 of the 2010 edition);
- Added the "measurement area" test method (see 5.1.1);
- Added the "Measurement of sample density" test method (see 5.1.2);
- Added the "repeatability test" test method (see 5.1.4, Appendix C);
- Changed "Type test of test surface" (see 5.2.6, 5.2.6 of the 2010 edition);
- Changed "Data Collection---Test Surface" (see 5.3, 5.3 of the 2010 edition);
- Changed "Data Analysis" (see 5.4, 5.4 of the 2010 edition);
- Added the "color representation of results" test method (see 5.5);
- Added the "electromagnetic compatibility" test method (see 5.7);
- Changed "Appendix B (Normative) Standard Display of Corneal Topographer" (see Appendix B, Appendix B of the 2010 edition).

This document is modified to adopt ISO.19980.2021 "Ophthalmic instruments - Corneal topographers".

This document has the following structural adjustments compared to ISO.19980.2021.

- According to the order of the appendices referenced in this document, Appendix D of this document corresponds to Appendix C of ISO.19980.2021.

The technical differences between this document and ISO.19980.2021 and their reasons

are as follows.

--- Replaced IEC 60601-1:2005 A1.2012 A2.2020 with the normative reference GB 9706.1 to adapt to my country's technical conditions;

--- Added normative reference document YY 9706.102 (see Chapter 2, 4.6, 5.7) to adapt to my country's technical conditions;

--- Added normative reference document JJF1059.1-2012 (see Chapter 2, Appendix C) to adapt to my country's technical conditions;

--- The terms and definitions of "ellipsoidal surface", "aspherical surface", "non-toric surface", "oblate surface" and "long oval surface" have been deleted (see ISO.19980.2021 3.14, 3.16.1, 3.16.2, 3.16.3, 3.16.4) to adapt to my country's technical conditions;

--- The requirements for the ellipsoidal test surface (see 5.2.6 of ISO.19980.2021) have been deleted to adapt to my country's technical conditions;

--- Deleted the high-order polynomial rotation surface (see A.3 of ISO.19980.2021) to adapt to my country's technical conditions;

--- Added "electrical safety" requirements (see 4.5) to adapt to my country's technical conditions;

--- Added "electromagnetic compatibility" requirements (see 4.6) to adapt to my country's technical conditions;

--- Added the "measurement area" test method (see 5.1.1) to increase operability and facilitate the implementation of the standard;

--- Added the "measurement of sample density" test method (see 5.1.2) to increase operability and facilitate the implementation of the standard;

--- Changed the repeatability test method (see 5.1.4, Appendix C, 5.1.2, Appendix D of ISO.19980.2021), added operable to facilitate the implementation of standards;

--- Changed the test surface verification accuracy requirements (see 5.2.5, 5.2.5 of ISO.19980.2021) to adapt to my country's technical conditions parts, increase operability and facilitate the implementation of standards;

--- Added the location of the measurement point (see 5.2.6) to increase operability and facilitate the implementation of the standard;

--- Changed formula (11) to formula (13) [see 5.4.3, formula (11) to formula (13) of ISO.19980.2021] to facilitate standardization.

implement;

--- Added the "color representation of results" test method (see 5.5) to increase operability and facilitate the implementation of the standard;

- Added the "electrical safety" test method (see 5.6) to increase operability and facilitate the implementation of the standard;
- Added the "electromagnetic compatibility" test method (see 5.7) to increase operability and facilitate the implementation of the standard;
- Deleted the requirements in 6 d) of the attached document [see 6 d) of ISO.19980.2021] to adapt to my country's national conditions;
- Changed the title of Appendix B, changing "Appendix B (Informative Appendix) Standard Display of Corneal Topography" to "Appendix B (Specification) (see Annex B of ISO.19980.2021) for standard display of corneal topographs implement.

The following editorial changes were made to this document.

- Changed the tolerance method of the radius of curvature of the spherical test surface in 5.2.6 (see 5.2.6, 5.2.6 of ISO.19980.2021) to adapt the national conditions of our country;
- Changed Table B.2 in Appendix B, swapped "B" and "S" in the header of Table B.2 and corrected some values, and changed "hue, brightness" Hue, saturation (HBS)" is changed to "hue, saturation, brightness (HSB)" (see Annex B, Annex to ISO.19980.2021 B) to facilitate the implementation of standards.

1 Scope

This document specifies the minimum requirements, accompanying documentation and marking for corneal topograph instruments and systems and describes the corresponding test methods.

This document applies to instruments or systems for measuring the shape of the human corneal surface.

NOTE The measurement result can be the surface curvature of a local area, the three-dimensional topographical dimensions of the surface, or other more comprehensive parameters used to characterize the surface characteristics.

This document does not apply to keratometers used in ophthalmic instruments.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB 9706.1 Medical electrical equipment Part 1: General requirements for basic safety and