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

YY/T 1949-2024

**Artificial intelligence medical device - Specific requirements for
datasets: colour fundus images of diabetic retinopathy**

人工智能医疗器械 数据集专用要求：糖尿病视网膜病变眼底彩照

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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. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This standard is proposed by the State Food and Drug Administration. This standard is under the jurisdiction of the technical authority responsible for standardization of artificial intelligence medical devices. This document was drafted by: Beijing Tongren Hospital Affiliated to Capital Medical University, National Health Commission Capacity Building and Continuing Education Center, Tsinghua University Shenzhen International Graduate School, China Food and Drug Inspection Institute, National Medical Products Administration Medical Device Technology Review Center, Zhongshan Eye Center of Sun Yat-sen University, the Second Affiliated Hospital of Zhejiang University School of Medicine, Peking Union Medical College Hospital of Chinese Academy of Medical Sciences, Beijing Hospital, Harbin The Second Affiliated Hospital of Binzhou Medical University, Beijing Eagle Eye Technology Development Co., Ltd., Yiwei Technology (Beijing) Co., Ltd., Beijing Eye and Optometry Co., Ltd. learn. The main drafters of this document are. Wei Wenbin, Yang Aiping, Dong Li, Shao Lei, Ma Lan, Li Jingli, Ma Zhaoyi, Liu Xiaoyin, Lin Haotian, Ye Juan, Chen Youxin, Dai Hong, Yuan Huiping, Song Chao, Yu Chen, Yu Weihong, Zhao Jing, Jin Kai, Lin Duoru, Gao Lin, Jiang Bo, Zhang Chuan, Li Fang, Meng Xiangfeng, Wang Hao, Hao Ye, Tang Chao, Ling Saiguang and Bai Yujing.

The diabetic retinopathy fundus color photo dataset is used for the research and development of artificial intelligence medical devices such as diabetic retinopathy auxiliary diagnosis software, Resources commonly used in training, testing, quality control and other

links have an important impact on product quality. This document is based on reference YY/T 1833.2-2022. Based on this, the special requirements for the color fundus photo dataset of diabetic retinopathy are proposed to guide the quality evaluation of such datasets. It is of reference significance to establish special evaluation criteria for other datasets. Special requirements for AI medical device datasets. Diabetic retinopathy fundus color photos

1 Scope

YY/T 1949 sets the rules for the dataset behind an AI screening tool for diabetic retinopathy. It specifies the particular requirements for colour fundus photograph datasets used in artificial intelligence medical devices for diabetic retinopathy, and the corresponding methods. Diabetic retinopathy screening was the first medical AI application approved at scale in China, and the quality of the training and test data, image acquisition, grading, annotation and the balance across disease stages, determines the algorithm more than the architecture does. It is the disease-specific companion to the general dataset requirements in YY/T 1833.2. For a developer of retinal screening software seeking Chinese registration, this is the standard the dataset documentation is assessed against, and the reference for anyone assembling or licensing fundus image data for that market.

This document specifies the specialized requirements for the diabetic retinopathy (DR) fundus color photo dataset for artificial intelligence medical devices. The corresponding test methods are described. This document is applicable to the research and development, production, quality control and other links of artificial intelligence medical devices for post-processing of diabetic retinopathy fundus color photos. According to the collection.

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.

YY/T 1833.1 Quality requirements and evaluation of artificial intelligence medical devices
Part

3 Terms and definitions

The terms and definitions defined in YY/T 1833.1, YY/T 1833.2-2022 and the following apply to this document.

3.1 diabetic retinopathy Diabetes causes damage to retinal microvessels, leading to a series of fundus lesions.

3.2 Digital color fundus photographs obtained using a fundus camera.

4.1.1 Overall description of the dataset

4.1.1.1 Dataset Type The dataset description should comply with the requirements of 4.1.1.1 in YY/T 1833.2-2022.

4.1.1.2 Dataset form The dataset description should comply with the requirements of 4.1.1.2 in YY/T 1833.2-2022.

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