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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1833.4-2023

Artificial intelligence medical device - Quality requirements and evaluation - Part 4: Traceability

人工智能医疗器械 质量要求和评价 第4部分：可追溯性

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents" Drafting. This document is Part 4 of YY/T 1833 "Quality Requirements and Evaluation of Artificial Intelligence Medical Devices". YY/T 1833 has been released The following sections are included.

2.General requirements for data sets;

3.General requirements for data annotation;

4.Traceability. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the national technical focal point for standardization of artificial intelligence medical devices. This document was drafted by: Chinese People's Liberation Army General Hospital, Medical Device Technical Review Center of the State Food and Drug Administration, Shanghai United Imaging Intelligent Medical Technology Co., Ltd., China Institute of Food and Drug Control, Sinopharm Medical Device Research Institute Co., Ltd., National Pharmaceutical Supervision and Administration Medical Device Technical Review and Inspection Greater Bay Area Center, Shanghai Changzheng Hospital, Infer Medical Technology Co., Ltd., Beijing An Deyizhi Technology Co., Ltd. The main drafters of this document. He Kunlun, Peng Liang, Zhang Nan, Zhao Xiaojing, Li Jiage, Yi Li, Ren Haiping, Wang Hao, Meng Xiangfeng, Hao Ye, Li Shu, Wang Jing, Liu Shiyuan, Xiao Yi, Wang Hui, Cao Desen, Wang Shaokang, Zhang Peifang.

In recent years, artificial intelligence medical devices have continued to develop and become an emerging direction in the field of medical device standardization. my country has initially established Artificial intelligence medical device standard system. In this standard system, YY/T 1833 "Quality Requirements and Evaluation of Artificial Intelligence Medical Devices" is Basic general standards provide guidance for carrying out standardization activities in subdivided areas and are planned to be composed of eight

parts.

1.Terminology. The purpose is to provide terminology for quality evaluation activities of artificial intelligence medical devices.

2.General requirements for data sets. The purpose is to propose general quality requirements and evaluation methods for data sets.

3.General requirements for data annotation. The purpose is to propose quality requirements and evaluation methods for the data annotation process.

4.Traceability. The purpose is to clarify the general requirements and evaluation methods for traceability of artificial intelligence medical devices.

5.Pre-trained model. The purpose is to standardize the quality of pre-trained models used in artificial intelligence medical devices.

6.Environmental requirements. The purpose is to standardize the operating environment condition requirements and evaluation methods of artificial intelligence medical devices.

7.Privacy protection requirements. The purpose is to strengthen the ability of artificial intelligence medical devices to protect the privacy of subjects.

8.Ethical requirements. The purpose is to realize the ethical requirements of artificial intelligence from a technical level and protect human rights and interests. This document aims to strengthen the traceability of artificial intelligence medical devices, and is important for standardizing the quality system of artificial intelligence medical devices and guiding artificial intelligence medical devices. It is of great significance to enable the healthy development of medical devices throughout their life cycle. Given that the current forms of artificial intelligence medical device products are independent software software or software components, this document emphasizes the particularity of artificial intelligence traceability based on the idea of software traceability. Due to the The scope of application and technology are still under constant development, and new quality requirements and evaluation methods proposed after fully considering applicability and risks are not subject to this article. software restrictions. At the same time, the traceability of the production process has been stipulated in the existing "Good Manufacturing Practice for Medical Devices" and this document does not require additional To standardize. Artificial intelligence medical device quality requirements and evaluation Part

1 Scope

YY/T 1833.4 is the part of the Chinese AI medical device series that deals with traceability. An AI device cannot be inspected the way a mechanical one can: its behaviour comes from data and training, so the only way to establish why it does what it does is to be able to trace a deployed model back through its version, its training and validation data, the annotation of that data, the preprocessing and the parameters used. This document sets out what has to

be recorded and linked, and how that record is evaluated. It is what makes an AI device auditable after release and what allows a failure to be investigated rather than merely observed. For a developer registering AI software in China, this is the part a reviewer applies to the development record.

This document stipulates the general requirements for traceability of artificial intelligence medical devices and describes the corresponding evaluation methods. This document applies to the traceability activities of the design and development process, use process and update process of artificial intelligence medical devices. This document does not apply to the circulation of artificial intelligence medical devices.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 42062 Application of medical device risk management to medical devices

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 and the following apply to this document.

3.1 traceability traceability The extent to which the design and development process, production process, use process and update process of artificial intelligence medical devices can be recorded.

3.2 Traceability matrix traceability matrix A matrix that records the relationship between two or more tasks. Example. A matrix recording the relationship between a given algorithm requirement and the algorithm design. [Source: GB/T 11457-2006, 2.1753, with modifications]

4 Traceability requirements

4.1 Overview The traceability of artificial intelligence medical devices is a key quality feature that supports the transparency, accountability, and auditability of artificial intelligence itself. people The realization of traceability of artificial intelligence medical devices requires activities in four stages. design and development process, production process, use process and update process. Put forward requirements to ensure the consistency of requirements, design, verification and validation during the life cycle of artificial intelligence medical

devices. The design and development process of artificial intelligence medical devices focuses on artificial intelligence algorithm requirements, algorithm design, algorithm implementation, algorithm verification and validation. The six major elements of identification, risk management, and data sets and their internal relationships are presented in the form of process documents and traceability matrices. The production process refers to the general requirements for the production process of medical device software. This document does not give special requirements. The usage process considers software functionality, software interface, and clinical deployment requirements. The update process considers product update activities at various stages.