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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1437-2023

Medical devices - Guidance on the application of GB/T 42062

医疗器械 GB/T 42062应用指南

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Table of Contents

Foreword

This document was drafted in accordance with the rules provided in GB/T 1.1-2020 Directives for standardization - Part

1.Rules for the structure and drafting of standardizing documents. This document replaces YY/T 1437-2016, Medical devices - Guidance on the application of YY/T 0316.Compared with YY/T 1437-2016, in addition to structural adjustments and editorial changes, the main technical changes are as follows: -- Change the scope of the document (see Clause 1; Clause 1 of the 2016 edition); -- Add the clause "Terms and definitions" (see Clause 3); -- Add the clause "General requirements for risk management system" (see Clause 4); -- Add the clause "Risk analysis" (see Clause 5); -- Add the clause "Risk evaluation" (see Clause 6); -- Add the clause "Risk control" (see Clause 7); -- Change "General considerations" to "General", and include the relevant contents of the 2016 edition changed (see 8.1;

6.1 of the 2016 edition); change "inputs and other considerations of evaluation of overall residual risk" to "inputs and other considerations", and include the relevant contents of the 2016 edition (see 8.2;

6.2 of the 2016 edition); add "possible approaches" (see 8.3); -- Add the clause "Risk management review" (see Clause 9); -- Change "production and post-production feedback loop" to "Production and post- production activities", and add relevant contents (see Clause 10; Clause 4 of the 2016 edition); -- Add "Identification of hazards and characteristics related to safety" (see Annex A); -- Add "Techniques that support risk analysis" (see Annex B); -- Add "Relation between the policy, criteria for risk acceptability, risk control and risk evaluation", and include the relevant contents of the 2016 edition (see Annex C; Clause 3 of the 2016 edition); -- Add "Information for safety and information on residual risk", and include the relevant contents of the 2016 edition (see Annex D; Clause 5 of the 2016 edition); -- Add "Role of standards in risk management", and include the relevant contents of the 2016 edition (see Annex E; Clause 2 of the 2016 edition); -- Add "Guidance on risks related to security" (see Annex F); -- Add "Components and devices designed without using ISO 14971" (see Annex G); -- Add "Guidance for in vitro diagnostic medical devices" (see Annex H). This document is equivalent to ISO/TR 24971.2020 Medical devices - Guidance on the application of ISO 14791, while the document type is adjusted from an ISO technical report to an industry standard of our country. Please note that some of the contents of this document may involve patents. The issuing organization of this document is not responsible for identifying patents. This document was proposed by National Medical Products Administration. This document shall be under the jurisdiction of National Technical Committee on Quality Systems and Corresponding General Aspects for Medical Devices of

Standardization Administration of China (SAC/TC 221). Drafting organizations of this document. Beijing Guoyi Huaguang Authentication Co., Ltd., China Institute of Food and Drug test, Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Neusoft Medical Systems Co., Ltd., Shanghai MicroPort Medical (Group) Co., Ltd., GE Hangwei Medical Systems Company Ltd., CONTEC Medical Systems Co., Ltd., Shanghai United Imaging Healthcare Co., Ltd., Shandong Weigao Group Medical Polymer Company Limited., Siemens Shanghai Medical Equipment Ltd., Lepu Medical Technology (Beijing) Co., Ltd. Main drafters of this document. Lou Xiaodong, Wang Huifang, Xu Huiwen, Wang Hongman, Wang Zhiqiang, Li Yong, Han Qiang, Li Xueyong, Li Rong, Liu Lina, Lu Zhi, Jiang Bo, Li Zhaohui, Sun Ye, Li Xin, Chang Jia, Liu Rongmin, Shao Yubo, Wang Tingting, Ai Yingying. The previous versions of this document and the documents which are replaced by this document are as follows: -- It was issued for the first time in 2016 as YY/T 1437-2016; -- This is the first revision.

1 Scope

YY/T 1437 is the guidance that explains how to actually apply GB/T 42062, the Chinese risk management standard for medical devices. GB/T 42062 says what a manufacturer must do; this document shows how it is done, working through the concepts that give trouble in practice: how hazards are identified, how risk is estimated when data are thin, what counts as an acceptable benefit-risk balance, and how risk management is kept alive across the product lifecycle rather than filed once at registration. Risk management is the spine of a Chinese technical file, and the risk management report is one of the first things a reviewer reads. At thirty-seven thousand words it is a substantial companion document. For any manufacturer registering a device in China, this is the text that says what the reviewer expects to find.

This document provides guidance on the development, implementation and maintenance of a risk management system for medical devices according to GB/T 42062-2022.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 42062-2022, Medical devices - Application of risk management to medical devices (ISO 14971.2019, IDT)

3 Terms and definitions

For the purposes of this document, the terms and definitions given in GB/T 42062-2022 apply.

4 General requirements for risk management system

GB/T 42062-2022 requires top management to review the suitability of the risk management process at planned intervals. The review of the suitability is a high-level review of the risk management process and can include reviewing the following aspects, for example.

5 Risk analysis

A hazard is a potential source of a harm. Depending on the specific situation, hazards can have different origins/natures. Examples of hazards are electricity, moving parts, infectious bacteria, chemicals, gases, sharp edges, high currents, temperature, and ionizing radiation.

6 Risk evaluation

GB/T 42062-2022 describes the process for risk evaluation. The standard, however, does not specify levels of acceptable risk. The criteria for risk acceptability are based on the manufacturer's policy for determining acceptable risk and are documented in the risk management plan.

7 Risk control

Several options exist to reduce risks associated with a medical device. These can be used alone or in combination. The manufacturer can explore different options to reduce the risks to acceptable levels in a reasonably practicable way. Deviations or errors in manufacturing processes can compromise the safety of medical devices, for example, by.

8 Evaluation of overall residual risk

The evaluation of overall residual risk is a challenging task that cannot be achieved by adding all individual risks numerically. The difficulty arises for the following reasons.