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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1473-2023

Guide for standardization for medical devices - Inclusion of safety aspects in standards

医疗器械标准化工作指南 涉及安全内容的标准制定

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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 1473-2016 "Guidelines for Standardization of Medical Devices Standardization Involving Safety Requirements". and Compared with YY/T 1473-2016, except for structural adjustment and editorial changes, the main technical changes are as follows: --Changed some terms, most of which originated from GB/T.20002.4-2015, and changed based on GHTF/SG1/N055.2009 definition of "manufacturer" (see Chapter 3, Chapter 2 of the.2016 edition); --Add guidance on the use of terms such as "safety", "safe", "effective" and "effectiveness" (see Chapter 4); --Added the general principles in the

process of developing medical device standards involving safety content based on risk (see 7.1); --Increased the preparatory work in the process of risk-based development of medical device standards involving safety content, including the identification of safety content The need for new or revised standards for content and the establishment of a risk management framework against which standards are developed (see 7.2.1, 7.2.2); --Increased the general rules drafted in the process of risk-based development of medical device standards involving safety content and the iterative process of risk management process (see 7.3.1, 7.3.2); --Changed "Hazards and dangerous situations related to medical devices" (see 7.3.4.3,

4.5.2 of the.2016 edition), and deleted "hazards related to patients Hazards (sources) and hazardous situations related to the use of situation" (see

4.5.4 of the.2016 edition), and "exposure to hazards (sources) and hazardous situations due to occupational reasons" was deleted (see.2016 edition version 4.5.5); -- Changed "Risk Estimation" (see 7.3.5,

4.7 of the.2016 edition); -- Changed "risks controlled by standards" to "identified risk controls" (see 7.3.7,

4.10.2 of the.2016 edition); added "Product standard requirements or process standard requirements as an appropriate risk control" (see 7.3.7.3), added "in the product standard or process Marked as a risk control measure in the standard" (see 7.3.7.4), added "packaging" (see 7.3.7.5); -- Added "Consider all identified hazards/hazardous situations" (see 7.3.11); --Deleted "promoting the implementation of ISO 14971 through product standards or process standards" (see Chapter 5 of the.2016 edition); -- Changed Figure 1 to better illustrate how the sequence of events converts a hazard into a hazardous situation that could result in injury (see Figure 1,.2016 Figure 1 of the annual edition); -- Added Figure 2 to illustrate the iterative process of risk management (see Figure 2). This document is modified to adopt ISO /IEC Guide 63.2019 "Guidelines for the Development of International Standards for Medical Devices Involving Safety Content". this document The technical differences from ISO /IEC Guide 63.2019 and their reasons are as follows: --The term "medical device" has been deleted. Since the Chinese standards and medical device regulations have definitions for "medical device", this document is no longer repeat. The following editorial changes have been made to this document. --In order to coordinate with the existing standard, the name of the standard is changed to "Guidelines for Medical Device Standardization Work Standardization Involving Safety Content". Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Medical Device Quality Management and General Requirements Standardization Technical Committee (SAC/TC 221). This document was drafted by: China National Institutes for Food and Drug Control, Beijing Guoyi Huaguang Certification Co., Ltd., Shanghai Medical Device

Inspection and Research Institute Research Institute, Shandong Medical Device and Drug Packaging Inspection Research Institute, Tianjin Medical Device Quality Supervision and Inspection Center, Shenzhen Mindray Biomedical Electronics Subsidiary Co., Ltd., Shanghai Minimally Invasive Medical Devices (Group) Co., Ltd. The main drafters of this document. Zheng Jia, Shao Yubo, Wang Meiying, He Jun, Hou Li, Li Libin, Wang Hongman, Li Yong, Li Zhaohui, Wang Huifang, Ye Shasha, Zhang Jianfeng, Ai Yingying. The release status of previous versions of this document and the documents it replaces are as follows: --First published as YY/T 1473-2016 in.2016; -- This is the first revision.

This document provides information on how standards writers can incorporate safety standards when developing medical device standards, including management system standards related to medical Aspects of content provide practical guidance. This document is based on the principles of risk management and GB/T.20002.4-2015, addressing the need. The security concepts described in this document are relevant to the protection of patients (i.e. recipients of healthcare), those providing healthcare and others who may be affected members are closely related. Safety is also concerned with harm to property or the environment. The methods described in this document aim to reduce the life cycle of medical devices (including design, production, distribution, installation, use, service, maintenance and destruction or Disposal), taking into account the entire life cycle of the medical device (including intended use and reasonably foreseeable misuse), the goal is to provide Achieve acceptable risks to people, property and the environment. Since different situations require different approaches to security, it is not possible to provide precise requirements and recommendations for every situation. Setting standards for medical device manufacturers versus setting standards for health care providers and medical institutions is an example of a different situation. However, if Following this document on a judged "use where applicable" basis will help develop standards that address safety content that is consistent with generally accepted consistent with the state-of-the-art technology. Guidelines for Standardization of Medical Devices Development of standards involving security content

1 Scope

YY/T 1473 is the guide for the people who write Chinese medical device standards, on how safety content should be built into them. It sets out how a drafting committee identifies the hazards a device class presents, how safety requirements are expressed so that they can actually be verified, how those requirements relate to risk management, and how a standard avoids either leaving a hazard unaddressed or specifying a solution where it should specify an outcome. It is a meta-standard: its readers are technical committees rather than manufacturers. But it explains the logic behind the safety clauses in every YY document, which makes it useful to anyone trying to understand why a Chinese standard demands what it demands, and to any organisation participating in Chinese standardisation work.

This document provides standards writers with requirements and recommendations for including safety-related content in medical device standards. These requirements and The recommendations are based on established risk management concepts and approaches. This document applies to the safety-related content of personnel, property, environment or a combination of these factors involved in medical device standards. In this document, the term "product" includes a single medical device or a combination of one or more medical devices (may also be used in combination with non-medical devices) composed system.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 hurt harm Injury or damage to human health, or damage to property or the environment. [Source: GB/T.20002.4-2015, 3.1, with modifications]

3.2 danger hazard potential source of harm (3.1). [Source: GB/T.20002.4-2015, 3.2]

3.3 hazardous situation Situation in which people, property or the environment are exposed to one or more hazards (3.2). [Source: GB/T.20002.4-2015, 3.4]

3.4 intended use intended use intended use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer (3.6) NOTE. The intended medical indication, patient population, body part or tissue type with which the medical device interacts, user characteristics, environment of use, and principle of operation are Typical elements of use.

3.5 life cycle life cycle All stages in the life of a medical device, from initial concept to eventual decommissioning and disposal.