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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1914-2023

Medical devices for human assisted reproductive technology - General requirements for instrument products

人类辅助生殖技术用医疗器械 器具类产品通用要求

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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. 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 China Institute for Food and Drug Control. This document was drafted by: China Institute of Food and Drug Control, Shandong Institute of Medical Device and Drug Packaging Inspection, Ruibo Biotechnology (China) Co., Ltd., Pacific Kangtai Scientific Instruments (Jinan) Co., Ltd., and Ayers (Zhejiang) Medical Technology Co., Ltd. The main drafters of this document. Li Chongchong, Han Qianqian, Mao Xin, Zhao Danmei, Wang Han, Lu Wenbo, Feng Huailiang, Bi Shengcheng, Qian Richeng, Fu Bufang, Liu Li, Chen Dandan, Liu Ye. Medical devices for human assisted reproductive technology General requirements for appliance products

1 Scope

YY/T 1914 sets the general requirements for the instrument products used in assisted reproduction: the catheters, pipettes, dishes, needles and other single-use items that handle gametes and embryos. What makes this class unusual is that the material has to be more than biocompatible in the ordinary sense, because an embryo exposed to a trace leachable for a few minutes may simply fail to develop, and no downstream test will recover it. This document specifies what such products have to satisfy and how it is demonstrated, including the embryo-directed testing that ordinary device standards do not require. IVF volumes in China are large and growing. For a manufacturer of ART consumables, this is the general text a Chinese registration is assessed against.

This document specifies the general requirements for medical devices used in human assisted reproductive technology, including requirements and test methods. This document applies to medical devices and appliances for human assisted reproductive technology,

including assisted reproductive catheters and assisted reproductive egg retrieval/ Sperm retrieval needles, and micro-tools for assisted reproduction.

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 14233.1-2022 Test methods for medical infusion, blood transfusion and injection equipment Part

3 Requirements and test methods

3.1 General The applicability and limit range of the following items can be determined based on the intended use and usage of the product, and can also be adjusted according to actual needs.

3.2 Physical properties

3.2.1 Dimensions Use general or special measuring tools for measurement. Product dimensions, such as length, diameter, capacity, etc., should comply with regulations.

3.2.2 Appearance Use normal or corrected vision to observe under specified conditions. The surface of the product should be clean, free of impurities, burrs, and cracks. If there is a mark Knowledge should be clear. The area where the product comes into contact with the gametes/embryos should be smooth.

3.2.3 Mechanical properties The main components of the product and their connections should be evaluated for mechanical properties according to the selected method (if applicable).

3.2.4 Other performance Performance that meets the intended design and use of the product, such as puncture performance, conical joints, sealing performance, corrosion resistance, special surface treatment