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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1884-2023

Fixed copper intrauterine device

固定式含铜宫内节育器

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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 National Technical Committee on Standardization of Family Planning Devices (SAC/TC169). This document was drafted by: Wuhan Weimin Medical Devices Co., Ltd., Shanghai Medical Device Inspection and Research Institute, Tianjin Hejie Medical Devices Equipment Co., Ltd., Chongqing Medical Equipment Quality Inspection Center. The main drafters of this document. Sun Xinhan, Yao Tianping, Wei Bo, Meng Mingjiang, Pan Ning, Qian Xinyi, Qin Na, and Fan Sijie. Fixed copper intrauterine device

1 Scope

YY/T 1884 covers the fixed copper intrauterine device, the frameless IUD anchored into the uterine wall rather than held in place by a plastic frame. It sets the requirements such a device has to meet and the test methods that verify them, covering the copper surface area and its release behaviour, the strength and security of the anchoring element, the removal characteristics, and the sterility and packaging of the product. Copper IUDs are the most used reversible contraceptive in China, and the frameless design exists to reduce the expulsion and pain associated with framed devices, which puts the anchoring mechanism at the centre of the safety case. The device stays in place for years, so the specification has to address long-term behaviour rather than initial performance. This is the text a Chinese registration is assessed against.

13.Qualification and analysis of degradation products of polymer medical devices Quantitative

YY/T 0640-2016 General requirements for passive surgical implants

YY/T 1404-2016 Technical requirements and test methods for copper used in

copper-containing intrauterine devices

YY/T 1471-2016 Technical requirements and test methods for indomethacin-containing silicone rubber for copper-containing intrauterine devices Pharmacopoeia of the People's Republic of China (2020 edition)

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 4240 stainless steel wire

GB/T 4340.1 Vickers hardness test of metallic materials Part

GB/T 16886.13-2017 Biological evaluation of medical devices Part

3 Terms and definitions

The following terms and definitions as defined in GB 11236-2021 apply to this document.

3.1 fixedtype The instrument is suspended in the uterine cavity by being fixed to the myometrium with non-absorbable sutures.

3.2 indomethacin A non-steroidal anti-inflammatory drug loaded on a copper-containing intrauterine device (IUD), which has anti-inflammatory and analgesic effects.

3.3 biodegradablepolymer Polymer materials that can be degraded by microorganisms or secretions in organisms under the action of enzymes or chemical substances within a certain period of time.

3.4 There is no hook force after the needle tip is loaded with external force.