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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Copper-bearing intrauterine contraceptive devices - Guidance
on the design, execution, analysis and interpretation of clinical
studies**

含铜宫内节育器 临床研究的设计、执行、分析和解释指南
(English Translation)

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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 modified to adopt ISO 11249:2018 "Guidelines for the design, execution, analysis and interpretation of clinical studies of copper intrauterine devices".

The technical differences between this document and ISO 11249:2018, and the reasons therefor, are as follows.

---The terms "case report form," "independent party," "informed consent process," and "placement device" have been removed from the terminology and definitions to better suit my country's national conditions.

(See Chapter 3 of ISO 11249:2018);

---ISO 14155 has been replaced with the normatively referenced YY/T 0297 to adapt to my country's national conditions (see Chapters 4 and 5);

---Change IUD (TCu380A) to a control medical device, and change "efficacy" to "effectiveness and safety" to suit my country's needs.

National conditions (see 5.2);

---ISO 7439 has been replaced with the normatively referenced GB 11236 to suit my country's national conditions (see Chapter 9);

---The requirements for using TCu380A as a control group and the specific number of cases in clinical studies have been revised to conform to GB 11236.

The country's national conditions (see 9.1);

---Parity checking has been removed and replaced with randomized grouping to suit my country's national conditions (see 9.3, ISO 11249:2018 9.3);

---Specific numerical requirements for pregnancy rate, expulsion rate, and termination rate have been removed to better suit my country's national conditions (see ISO 11249:2018).

Chapter 9);

---The relevant statements regarding the use of TCu380A as a control group and the related regulations on the selection requirements of reference standards have been deleted to adapt to my country's national standards.

National conditions (see 9.5 of ISO 11249:2018);

---The issuance policy has been removed to adapt to my country's national conditions (see

Chapter 12 of ISO 11249:2018).

The following editorial changes have been made to this document.

---ISO 14155 has been replaced by YY/T 0297 (see Chapter 1) as an informative reference;

---ISO 7439 has been replaced with GB 11236 (see 7.1, Chapter 8) for informational purposes;

---ISO 14971 has been replaced with GB/T 42062 (see 7.4), which is cited as informative.

---Replaced with the reference material "Clinical Practice Guidelines and Technical Operation Specifications - Family Planning Volume" (2017 Revised Edition) Medical Standards for the Selection of Contraceptive Methods and Practical Recommendations for the Selective Use of Contraceptive Methods (see 9.3, Chapter 10, Appendix A and...) Appendix B).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Contraceptive and Obstetric Devices (SAC/TC169).

1 Scope

This document provides guidance on the design and implementation of clinical trials aimed at determining the performance characteristics of novel copper-containing intrauterine devices (IUDs), and also offers...

It provides data analysis after the study is completed, as well as suggestions for manufacturers, researchers, and regulatory agencies on how to interpret the results.

This document applies to sponsors, monitors, researchers, ethics committees, regulatory agencies, and other stakeholders involved in medical device compliance assessments.

Relevant agencies provide support.

This document does not address certain clinical trial-related issues, including participant compensation, confidentiality of participants and their records, and ethics committees.

Operation, etc. For these issues and more detailed clinical trial design guidelines, please refer to YY/T 0297.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB 11236 Technical requirements and test methods for copper-containing intrauterine devices (GB 11236-2021, ISO 7439:2015, MOD) YY/T 0297 General Requirements for Quality of Clinical Trials of Medical Devices

3 Terms and Definitions

The following terms and definitions apply to this document.

Device-related adverse events (ADE) Adverse events related to the use of the investigational medical device.

Note 1: This definition includes adverse events caused by the use, implantation, installation, operation, or malfunction of the experimental medical device.

Note 2: This definition includes events caused by incorrect use or intentional misuse.

Note 3: If the control in a clinical trial is a medical device, then "control medical device" is included.

Adverse events (AE)

refers to adverse medical events that occur during clinical trials of medical devices, regardless of whether they are related to the investigational medical device.

Note 1: This definition includes events related to experimental or control medical devices.

Note 2: This definition includes events related to surgery.

Note 3: For users or others, this definition is limited to events related to the experimental or control medical device.

audit

The sponsor shall organize a systematic and independent review of the activities and documentation related to the clinical trials of medical devices to determine the compliance of such activities.

Whether the recording, analysis, and reporting of data comply with the clinical trial protocol and related document requirements.