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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Copper-bearing contraceptive intrauterine devices - Requirements and tests

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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 of Standardization Documents"

Drafting.

This document replaces GB 3156-2006 "OCu intrauterine device", GB 11234-2006 "uterine cavity-shaped intrauterine device",

GB 11235-2006 "VCu intrauterine device", GB 11236-2006 "TCu intrauterine device". This document integrates GB 3156-2006,

Part of GB 11236-2006, GB 11235-2006, GB 11234-2006.Compared with GB 11236-2006, except for structural adjustment

In addition to the overall and editorial changes, the main technical changes are as follows.

a) Added "Terms and Definitions" (see Chapter 3);

b) Added "expected performance" (see Chapter 4);

c) Subdivide "product features, basic dimensions, materials" into "design attributes" and "materials", and include the relevant content after changes (see

Chapter 5, Chapter 6, Chapter 3 of the.2006 edition);

d) Change "requirements" to "design attributes", and include the relevant contents of the.2006 edition (see Chapter 7,.2006 edition

Chapter 4);

e) Change the "test method" to "design evaluation", and include the relevant content of the.2006 edition (see Chapter 7,.2006 edition)

Chapter 5);

f) Added "X-ray detectability" (see 5.6);

g) Added "barium sulfate content" (see 5.7);

h) Added "preclinical evaluation" (see 7.6);

i) Added "Clinical Evaluation" (see 7.7);

j) Added "Information Provided by Manufacturer" (see Chapter 11).

This document uses the redrafting method to modify and adopt ISO 7439.2015 "Requirements and Tests for Copper-Containing Intrauterine Devices". This document and

The technical differences of ISO 7439.2015 and their reasons are as follows.

---Regarding normative reference documents, this document has been adjusted with technical differences to adapt to my country's technical conditions and adjustments.

The situation is collectively reflected in "2 Normative Reference Documents", and the specific adjustments are as follows.

* Replace ISO 10993.1 with GB/T 16886.1 which is equivalent to adopting international standards;

* Replace ISO 14155 with YY/T 0297 which is equivalent to adopting international standards;

* Replace ISO 14971 with YY/T 0316 which is equivalent to adopting international standards;

* Replace ISO 15223-1 with YY/T 0466.1 which is equivalent to adopting international standards;

* Replaced the European Pharmacopoeia with the Pharmacopoeia of the People's Republic of China (2020 edition)

--- Amend "Intrauterine Device" to "Copper Intrauterine Device" (see 3.1);

---Added "If necessary," (see 3.3);

---Deleted specific values in clinical performance (see 4.2);

--- Modified "The tail wire and copper should be an inseparable part of the IUD" to "The tail wire (if any) and copper should be an inseparable part of the IUD"

(See 5.1);

--- Modified "The nominal length of the IUD should be <=36.2mm, and the nominal width of the IUD should be <=32.3mm." is the "nominal length of the IUD"

And the nominal width should be specified by the manufacturer. "(See 5.3.1);

---Added "(if any)" (see 5.3.3);

--- Deleted "The part of the placer in contact with the cervix, its maximum nominal outer

diameter shall not be greater than 5mm." (see 5.3.4);

--- Modify the size tolerance of the placer "+/-5%" to "+/-10%" (see 5.3.4);

---Added "IUD (if there is tail wire, including tail wire) should bear the tensile strength see Table 1." (see 5.4);

---Deleted stability (see 5.5 in ISO 7439.2015);

--- Amend "Intrauterine Inspection" to "X-ray detectability" (see 5.6);

--- Amend "should ensure that the purity of copper reaches at least 99.9%" to "should ensure that the purity of copper on the final product reaches at least 99.99%."

(See Chapter 6);

---The operation method of tensile test without tail wire IUD has been added (see 7.3.3);

---Modified the "European Pharmacopoeia" as the Pharmacopoeia of the People's Republic of China (see 7.5.1 and 7.5.2);

--- Deleted "According to this classification, the intrauterine device is a mucosal contact device, and the following auxiliary tests should be considered." (see 7.6);

--- Deleted the number of specific cases of clinical evaluation in "clinical evaluation" and "clinical evaluation should be carried out in accordance with YY/T 0297" (see 7.7);

--- Added "Compile clinical evaluation report in accordance with YY/T 0297." (see 7.7);

--- Modify the "CE number according to the EU directives on medical devices" to "registration certificate number" (see 11.4).

Introduction

Although any foreign objects placed in the uterus will show a certain contraceptive effect, the copper-containing intrauterine device is through the continuous release of copper ions

Method to achieve contraception. Copper ions can effectively improve copper-containing intrauterine birth control by interfering with the function of some enzymes, slowing down sperm movement and preventing fertilization, etc.

The contraceptive effect of the device.

The contraceptive effect of the copper-containing intrauterine device is better than that of the pure plastic IUD.

The medicated intrauterine device and the copper-free intrauterine device can also refer to this document.

The copper-containing intrauterine device is a medical device, such as the design, placement device, technical characteristics, and placement technology should be used

when major changes occur

verify.

Technical requirements and test methods for copper-containing intrauterine devices

1 Scope

This document specifies the expected performance, design attributes, materials, design evaluation, manufacturing and inspection, sterilization, packaging and manufacturing of copper-containing intrauterine devices.

Information provided by the manufacturer.

This document applies to single-use copper-containing intrauterine devices and their placement devices.

This document does not apply to intrauterine devices with plastic as the main body or mainly for the release of progesterone.

2 Normative references

The content of the following documents constitutes an indispensable clause of this document through normative references in the text. Among them, dated quotations

Only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

This document.

GB/T 16886.1 Biological Evaluation of Medical Devices Part 1.Evaluation and Testing in the Process of Risk Management (GB/T 16886.1-

2011, ISO 10993.1.2009, IDT)

YY/T 0297 Clinical Investigation of Medical Devices (YY/T 0297-1997, ISO 14155.1996, IDT)

YY/T 0316 Application of medical device risk management to medical devices (YY/T 0316-2016, ISO 14971.2007 correction

Version, IDT)

YY/T 0466.1 Medical devices are used for medical device labeling, marking and providing information symbols. Part 1.General requirements

(YY/T 0466.1-2016,ISO 15223-1.2012,IDT)

YY/T 0640-2016 General requirements for passive surgical implants (ISO 14630.2012, IDT)

Pharmacopoeia of the People's Republic of China (2020 Edition)