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

GB/T 44875-2024

Fallopian rings - Requirements and test methods

输卵管结扎环 技术要求与试验方法

(English Translation)

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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 is modified to adopt ISO 19351:2019 "Technical requirements and test methods for tubal ligation rings".

The technical differences between this document and ISO 19351:2019 and their reasons are as follows.

- Added GB/T 2828.1-2012 and Pharmacopoeia of the People's Republic of China to adapt to my country's technical conditions (see 4.1);
- Added "thickness" requirements (see 4.2.1);
- Deleted "for a period of 4 years", changed "within the temperature range of 0°C~50°C" to "within the temperature range claimed by the manufacturer", and Adapt to my country's technical conditions (see 4.3.2);
- Added the requirement of "monitoring of ethylene oxide residual content" (see 4.3.6);
- ISO 11135 (see 4.3.6) is replaced by the normative reference GB 18279 to adapt to my country's technical conditions;
- ISO 11137-1 (see 4.3.6) is replaced by the normative reference GB 18280.1 to adapt to my country's technical conditions;
- Replaced ISO 11137-2 (see 4.3.6) with the normative reference GB 18280.2 to adapt to my country's technical conditions;
- Added the requirements for "pyrogen" (see 4.4);
- ISO 10993-1 (see 4.4) is replaced by the normative reference GB/T 16886.1 to adapt to my country's technical conditions;
- ISO 10993-3 (see 4.4) is replaced by the normative reference GB/T 16886.3 to adapt to my country's technical conditions;
- ISO 10993-5 (see 4.4) is replaced by the normative reference GB/T 16886.5 to adapt to my country's technical conditions;
- Replaced ISO 10993-6 (see 4.4) with the normative reference GB/T 16886.6 to adapt to my country's technical conditions;
- ISO 10993-10 (see 4.4) is replaced by the normative reference GB/T 16886.10 to adapt to my country's technical conditions;
- Replaced ISO 10993-11 (see 4.4) with the normative reference GB/T 16886.11 to adapt

to my country's technical conditions;

--- Replaced ISO 15223-1 (see Chapter 6) with the normative reference YY/T 0466.1 to adapt to my country's technical conditions;

--- Replaced ISO 15223-2 (see Chapter 6) with the normative reference YY/T 0466.2 to adapt to my country's technical conditions;

--- Deleted "clinical evaluation" to adapt to my country's technical conditions (see 4.6);

--- Changed the "Storage Conditions" from "at 0°C~50°C" to "within the temperature range claimed by the manufacturer" to adapt to my country's climatic conditions (see Chapter 5);

--- Changed the acceptance criteria for sterility to "test according to the method in the Pharmacopoeia of the People's Republic of China and meet the sterility requirements" to adapt to my country's technical conditions (see A.2, B.1, I.3).

--- Deleted the machine type and drive type (see D.2.2, E.3, H.2);

--- Added "until the tubal ligation ring completely enters the tubular protrusion with an outer diameter of 5.5 mm" (see E.4);

--- Added "Method C. Other controlled environments" (see I.2);

--- Changed the temperature and humidity conditions of real-time aging to adapt to my country's technical conditions (see I.4);

--- Added other controlled environments such as thermal aging chambers (see J.2).

Introduction

The tubal ligation ring is a device that achieves permanent contraception. The ring is made of medical silicone rubber band and is inserted through laparoscopic surgery.

The ligation ring is placed on each fallopian tube to cut off the blood supply to the fallopian tube and block the fallopian tube.

The tubal ligation ring blocks the egg from entering the uterus, thus preventing fertilization. The tubal ligation ring is supplied sterile and packaged in sets of two.

This document does not mention the requirements for raw materials of tubal ligation rings, and manufacturers are responsible for their own evaluation.

This document covers the accumulated experience of manufacturers and buyers in marketing products.

Technical requirements and test methods for tubal ligation rings

1 Scope

This document specifies the basic requirements for tubal ligation rings and describes the corresponding test methods.

This document applies to tubal ligation rings that block a woman's fallopian tubes for permanent contraception.

This document does not apply to applicators or other accessories used to place tubal ligation rings.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 2828.1-2012 Sampling procedures for inspection by attributes Part 1: Sampling for batch inspection based on acceptance quality limit (AQL) Plan (ISO 2859-1:1999, IDT)
GB/T 16886.1 Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) GB/T 16886.3 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (GB/T 16886.3-2019, ISO 10993-3:2014, IDT) GB/T 16886.5 Biological evaluation of medical devices Part 5: In vitro cytotoxicity test (GB/T 16886.5-2017, ISO 10993-5:2009, IDT) GB/T 16886.6 Biological evaluation of medical devices Part 6: Test for local reactions after implantation (GB/T 16886.6-2022, ISO 10993-6:2016, IDT) GB/T 16886.10 Biological evaluation of medical devices Part 10: Irritation and skin sensitization tests (GB/T 16886.10-2024, ISO 10993-10:2021, IDT) GB/T 16886.11 Biological evaluation of medical devices Part 11: Systemic toxicity tests (GB/T 16886.11-2021, ISO 10993-11:2017, IDT) GB 18279 Sterilization of healthcare products - Requirements for the development, validation and routine control of ethylene oxide sterilization processes for medical devices (GB 18279-2023, ISO 11135:2014, MOD) GB 18280.1 Radiation sterilization of health care products Part 1: Development, validation and routine control of sterilization processes for medical devices (GB 18280.1-2015, ISO 11137-1:2006, IDT) GB 18280.2 Radiation sterilization of health care products Part 2: Establishing the sterilization dose (GB 18280.2-2015, ISO 11137-2:2006, IDT) YY/T 0466.1 Symbols for medical devices used for information provided by manufacturers Part 1: General requirements YY/T 0466.2 Medical devices Symbols for labelling, marking and providing information on medical devices Part 2: Development of symbols, Select and confirm Pharmacopoeia of the People's Republic of China