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Male condoms - Requirements and test methods for condoms made from polyurethane

男用避孕套 聚氨酯避孕套的技术要求与试验方法

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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. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Standardization Technical Committee of Family Planning Devices (SAC/TC169). This document is drafted by: Lanzhou Ketian Health Technology Co., Ltd., Shanghai Medical Device Testing Institute, Henan Provincial Medical Device Inspection Institute, Qingdao London Durex Co., Ltd. (Reckitt Benckiser (China) Investment Co., Ltd.), Wuhan Jieshibang Sanitary Products Co., Ltd., Gansu Provincial Medical Therapeutic Device Inspection Institute, Hefei Ketian Water-based Technology Co., Ltd. The main drafters of this document. Chen Liang, Yao Tianping, Wang Haitao, Wang Zhiyuan, Qian Xinyi, Jia Yunkun, Ren Hansheng, Feng Linlin, Zhang Junzi, Sun Kaifeng, Ren Juan, Chen Dalei, Wang Zewei, Xu Huiping, Li Weihu, Zhu Youkui.

Polyurethane condoms can be made of pure polyurethane latex, or a mixture of polyurethane latex and natural rubber latex. Intact polyurethane films can isolate infectious agents of human immunodeficiency virus (HIV), sexually transmitted diseases (STIs) and

sperm effect. A large number of comparative studies have proved that the correct use of polyurethane condoms can effectively prevent pregnancy and reduce the transmission of STIs, including HIV. broadcast risk. For condoms to be effective in preventing pregnancy and preventing the transmission of STIs, condoms should be the proper size, free from pinholes, and strong enough to ensure Ensure that there is no breakage during use, suitable packaging protects the product during the storage period, and appropriate labels are convenient for consumers to use. all of these Issues are addressed in this document. Condoms are medical devices, in order to ensure high-quality products, they should be produced under a good quality management system. quality management See GB/T 19000 family of standards and YY/T 0287, and see YY/T 0316 standard for risk management requirements. In order to ensure the safety of the condom, the condom itself and any lubricants, additives, marking materials, accessories, individual packaging Neither the material nor the powdered substance should have or release toxicity, cause allergies and local irritation or other hazards. Manufacturers should focus on contraception Set of studies related to chemical characterization. Condoms are non-sterile medical devices, but manufacturers are advised to take appropriate measures to minimize microbial contamination of products during production and packaging minimized. This document recommends that manufacturers preemptively reduce microbial contamination during production. The test method used to determine the level of microbial contamination See appendix G for details. For condoms with a thickness less than or equal to 0.022mm claimed by the manufacturer, the corresponding bursting volume and bursting pressure should be formulated by the manufacturer indicators, and submit supporting data to regulatory authorities or certification bodies to prove the safety and effectiveness of the product. This document recommends that manufacturers conduct stability tests on new types of condoms before they are placed on the market to determine the shelf life and begin Real-time stability test studies, Chapter 10 specifies these requirements. Real-time stability testing can be performed by manufacturers on their marketed products part of regulatory requirements. Use these requirements to ensure that the manufacturer has sufficient data to support its claimed storage before the product is placed on the market. These data are available to regulators, third-party laboratories and purchasers for review. These requirements are also used to guide third parties in conducting long-term The need for long-term stability studies. Male Condoms Polyurethane Condoms Technical requirements and test methods

1 Scope

YY/T 1850 covers male condoms made from polyurethane rather than natural rubber latex, the alternative for users with a latex allergy. It sets the technical requirements such condoms have to meet and the test methods that verify them, covering the dimensions, the bursting volume and pressure, freedom from holes, the strength of the material and the packaging and shelf life that keep the product intact until use. Polyurethane behaves

differently from latex, so the test methods written for latex condoms cannot simply be transferred, and this document supplies the ones that apply. A condom is a barrier device whose failure has consequences that are not recoverable, which is why the sampling and testing regime is unusually strict. For a manufacturer or importer this is the text a Chinese registration and a batch release are judged against.

This document specifies the male condoms made of polyurethane latex, which are intended for use by consumers as contraception and to help prevent sexually transmitted diseases The minimum technical requirements and test methods. This document is applicable to 100% polyurethane condoms and other composite male condoms with polyurethane latex as the main material.

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, 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 2828.1-2012 Counting sampling inspection procedure Part

1.Batch-by-batch inspection sampling retrieved by acceptance quality limit (AQL) plan

GB/T 7544 Technical requirements and test methods for natural rubber latex male condoms

GB/T 16886.1 Biological evaluation of medical devices Part

3 Terms and Definitions

YY/T 1777 and GB/T 2828.1-2012 and the following terms and definitions apply to this document.

3.1 The worst process average quality level that can be tolerated when a continuous series of lots is submitted for acceptance sampling. [Source: GB/T 2828.1-2012, 3.1.26]

3.2 male condom male condom Medical devices that enable consumers to achieve the purpose of contraception and prevention of STIs by covering or wrapping the penis during sexual intercourse. [Source: YY/T 1777-2021, 3.2]

5 Cytotoxicity test in vitro

GB/T 16886.10 Biological evaluation of medical devices - Part

10 Irritation and skin sensitization tests

GB/T 19000 Quality Management System Fundamentals and Terminology

YY/T 0316 Application of Medical Device Risk Management to Medical Devices

YY/T 0466.1 Symbols for Medical Device Labeling, Marking and Information Provision for Medical Devices Part