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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0720-2023

Single-use maternity kits - General requirements

一次性使用产包 通用要求

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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 replaces YY/T 0720-2009 "Disposable Birth Packs for Natural Delivery". Compared with YY/T 0720-2009, except for In addition to structural adjustments and editorial revisions, the main technical changes are as follows:

---Changed the scope of application (see Chapter 1, Chapter 1 of the.2009 edition);

--- Changed the production package configuration and technical requirements (see 5.1, 5.1 of the.2009 edition);

--- Increased the performance requirements of the absorbent pad (see Table 1);

--- Changed the performance requirements of the headgear (see Table 1, Table 1 of the.2009 edition);

--- Added the performance requirements for medical nonwoven compresses, and changed the test method (see Table 1, Table 1 of the.2009 edition);

--- Added performance requirements for umbilical clamps and umbilical cords (see Table 1);

--- Added special requirements for caesarean section (see 5.2). 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 was drafted by: Shandong Institute of Medical Device and Drug Packaging Inspection, Shanghai Institute of Medical Device Inspection, Zhende Medical Supplies Co., Ltd., Henan Yadu Industrial Co., Ltd., Jiangsu Medical Device Inspection Institute, Beijing Medical Device Evaluation and Inspection Center. The main drafters of this document. Ai Chongchong, Yao Tianping, Lu Jianguo, Zhang Zhengnan, Zheng Dixin, Zhang Xiuli, Yao Xiujun, Qian Xinyi, Gao Yanbo, Duan Shuxia, Chen Yang, Fang Ping, Liu Xueting, Du Heng.

The production package is mainly composed of production orders, equipment lists and other isolation and protective equipment, which are listed as the basic configuration in the production package in this document. According to clinical needs If required, surgical gowns, head caps, gloves, masks and other related equipment can also be used as part of the production package, and this document lists them as optional items in the production package. configuration. The equipment in the delivery bag is used in the delivery room with certain purification requirements. release) to a minimum. Production packages should be produced under purification conditions suitable for the environment in which they are used. In addition to the characteristics required in this document, the ability to effectively isolate devices in the delivery package is also of clinical importance. However, due to The isolation ability of the isolation article is affected by many factors such as the shape design, size, user habits, wearing convenience, and wearer's own conditions of the device. Therefore, this document does not include requirements in this regard, and does not specify the requirements of each group in the production package. It only stipulates the size and tolerance of each component of the cesarean section sheet, and lists the typical cesarean section sheet size in Appendix A. size example. In addition, encouraging innovation is also the reason why this document does not specify these requirements. Since most of the devices in the production package are made of highly absorbent materials and are relatively large in size, sterilization with ethylene oxide will result in a higher ethylene oxide concentration. Residues (absolute content), which will bring a certain degree of harm to relevant personnel (doctors, mothers and newborns) in the delivery room, especially newborns. Therefore, it is not appropriate to use ethylene oxide sterilization as the preferred sterilization method for production packages. If ethylene oxide is used for sterilization, it is advisable to use an effective method to make the environment Oxygen residues are reduced to a minimum. The production bag is one of the most used surgical bags, and its main components are advocated to be made of environmentally friendly raw materials that are easy to discard. General requirements for single-use product packaging

1 Scope

YY/T 0720 sets the general requirements for the single-use maternity kit, the pre-packed sterile set of drapes, gloves, cord clamp, dressings and instruments assembled for a delivery. It covers what such a kit has to contain and how the contents have to perform, the sterility and packaging of the pack as a whole, and the marking and information that accompany it, together with the test methods that verify them. The kit exists so that a delivery in a county hospital or a rural clinic starts from a known, sterile baseline rather than from whatever is at hand, which makes it a public health product as much as a medical device. Because a kit is an assembly, the standard has to govern both the individual components and the pack. This is the document a Chinese registration and a hospital procurement contract refer to.

YY 0594 General requirements for surgical gauze dressings

YY 0852-2011 Disposable sterile surgical film

YY/T 0854.2-2011 Performance requirements for cotton nonwoven surgical dressings Part

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 7543 Disposable sterile rubber surgical gloves

GB/T 14233.1-2008 Test methods for medical infusion, blood transfusion and injection equipment Part

3 Terms and Definitions

The following terms and definitions defined in YY/T 0506.1 apply to this document.

3.1 cesareankits caesareankits A group of medical devices packaged together, intended for use in caesarean sections.

3.2 natural birth kits maternitykits A group of medical devices packaged together, intended to be used in combination devices for natural childbirth procedures.

3.3 Production order maternitydrape The general term for products whose main purpose is isolation in the production package, but does not include medical gloves, head caps and instrument sheets.

Note. It is mainly divided into cushion sheet (3.5) and cover sheet (3.7).

3.4 In cesarean section, it is used to cover or wear on the parturient body or some parts of the body, mainly to isolate the pollution source (such as skin) from the parturient.