

Disposable Sterile Obstetric Kit

一、Product name, model and specification

Product name: Disposable sterile obstetric kit

Model specification: Delivery type, abortion type

二、Name, address, production address, contact information and after-sales service unit of the registered person/manufacturer

1、Name: Hunan Zhenheyikang Medical Instrument Co.,LTD

2、Address: No.6 Building Jingxiang Energy, No.55 Xiaguang east road, Gaoxin district Xiangtan, Hunan

3、Production address: NO.6 Building, NO.8 building, 3rd and 4th floor Jingxiang Energy, No.55 Xiaguang east road, Gaoxin district Xiangtan, Hunan, NO 19 Chutian Road, Yuetang District, Xiangtan City, Hunan

4、Contact number: +86 17711627084

5、After-sales service unit: Hunan Zhenheyikang Medical Instrument Co.,LTD

三、Manufacturing License NO: Hunan Medical Products Administration Production Licence No. 20150013

四、Product Registration Certificate No, Product Technical Requirements No: HNFDA Certified 20182140082

五、Structure and composition, scope of application

The product consists of basic configuration: sheet, cover sheet, instrument sheet and auxiliary configuration surgical clothes, surgical masks, medical cap, disposable rubber surgical gloves, gauze bandage, gauze pads, trouser leg, bag sheet, plastic tweezers / umbilical cord clip, medical skimmed cotton ball, umbilical cord protection, non-absorbent suture / umbilical cord rope and towel. After ethylene oxide sterilization, the residual amount should be no greater than 10ug / g.

Products for medical institutions of obstetrics and gynecology clinical delivery and abortion.

六、Use method: open the bag can be used

七、Contraindications, precautions, warnings and reminders

Product contraindications: None

Damaged packaging prohibited use, expired products prohibited use;

Disposable use, please destroy after use

Avoid high temperature, humidity, direct sunlight

八、Interpretation of graphics, symbols, abbreviations and other contents used in medical device labels



一次性使用



参考使用说明书



包装破损切勿使用



环氧乙烷灭菌



无菌

九、Installation and use instructions or illustrations

This product does not need to be installed, open the bag can be used.

十、Product maintenance and maintenance methods, special storage, transportation conditions, methods

Products should be stored in relative humidity $\leq 80\%$, non-corrosive gas and well-ventilated indoor, ordinary transport, in the transportation, storage process should be kept clean and pollution-free, strictly prohibited rain and snow immersion.

十一、Date of production, shelf life or expiration date

Valid for two years, production batch number, production date, expiry date please refer to the small package or qualification label.

十二、Accessories list, including accessories, appendix, lossitage replacement cycle and replacement method description

This product has n o accessories

十三、Date and version of preparation or revision of the specification

This specification was revised in February 2023, version 2023.