

# 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, 3<sup>rd</sup> and 4<sup>th</sup> 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.