

# Disposable Sterile Surgical Kit

## 一、 Product name, model and specification

Model specification: Disposable sterile surgical kit

Model and specifications: Type I (interventional), type II (ophthalmic), type III(abdominal), type IV (joint replacement), type V (orthopedic), type VI (brain)

## 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 20182140084

## 五、 Structure and composition, scope of application

产品由基本配置:手术衣、口罩、医生帽、垫单、孔巾、医用纱布块、一次性使用灭菌橡胶外科手套、大、小包单和辅助配置:塑料镊子、托盘、医用脱脂棉球、一次性使用助推器、医用棉签、手术刀、手术钳、医用胶带、创口贴、输液贴、医用弹性绷带、废液收集袋、量杯、塑料试管、塑料碗、剪刀、尺子、定位条、载玻片组成。包内各配件应无污染、无破损、无臭、无味,经缝制的产品应针距均匀,无跳针、脱针现象。塑料配件应光洁、色泽均匀,不应有毛刺、飞边和裂纹等现象。产品无菌供应,环氧乙烷灭菌,环氧乙烷残留量应 $\leq 10\mu\text{g/g}$ 。 Products basic configuration: surgical gowns, masks, doctor cap, pad, scarves, medical gauze block, disposable sterilized rubber surgical gloves, large, small and auxiliary configuration: plastic tweezers, tray, medical skim cotton ball, disposable booster, medical cotton swabs, scalpel, surgical forceps, medical tape, wound, infusion, medical elastic bandage, waste liquid collection bag, cup, plastic, plastic tube, plastic bowl, scissors, ruler, positioning strip, slide. All accessories in the package shall be pollution-free, damaged, odorless and tasteless. The sewn products shall be uniform with no phenomenon. Plastic accessories should be smooth, uniform color, should not have burrs, flying edge and cracks. Supply sterile, ethylene oxide sterilized, and ethylene oxide residue should be  $10\mu\text{g/g}$ .

Products are used in the operating room of medical institutions.

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 no accessories

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

This specification was revised in February 2023, version 2023.