

湖南臻和亦康医疗用品有限公司

HUNAN ZHENHEYIKANG MEDICAL INSTRUMENT CO, LTD

检 验 报 告 单

INSPECTION REPORT

编号/NO: JL-ZG-CG016

A/0

产品名称 Product name		一次性使用换药包 Disposable dressing set	生产批号 Lot No	20221224
型号规格 Specification		清洗型 Cleaning type	灭菌批号 Sterilization Lot No	20221229-237B
检验日期 Inspection Date		2023.01.03	批 量 Sampling Quantity	/
检测项目 Test item		标准要求 Standard		检验结果 Inspection result
物 理 p h y s i c s	2.1 配置、外观要求 Content Appearance	配置：见附件；外观要求：包内各配件应无污染、无破损、无臭、无味现象。塑料配件应光洁、色泽均匀，不应有毛刺、飞边和裂纹等现象。 All the materials should be no pollution no dirty spot,no smell;all the elastic materials should be bright and clean colour and lustre is uniform.		合格 Qualified
	2.2 包巾、垫巾抗渗水性 Wraps and pads are hydropermeable	关键区域 $\geq 20\text{cmH}_2\text{O}$ 非关键区域 $\geq 10\text{cmH}_2\text{O}$ Critical region $\geq 20\text{cmH}_2\text{O}$ non-critical region $\geq 10\text{cmH}_2\text{O}$		合格 Qualified
	2.3 医用纱布块 Gauze swab	下沉时间不超过 10s Sinking time less than 10s 每平方米质量应不低于 39g. Weight/square meter more than 39g.		合格 Qualified
	2.4 酒精+棉球 Alcohol + cotton ball	以对 30 人皮肤表面自然菌的平均杀灭对数值 ≥ 1.00 ,可判为消毒合格 The average killing value of natural bacteria on the skin surface of 30 people ≥ 1.00 , which can be judged as disinfection		合格 Qualified

	2.5 碘伏+棉球 Iodine volt + cotton ball	以对 30 人皮肤表面自然菌的平均杀灭对数值 ≥ 1.00 ,可判为消毒合格 The average killing value of natural bacteria on the skin surface of 30 people ≥ 1.00 , which can be judged as disinfection	合格 Qualified
	2.6 镊子 夹持力 Tweezer chucking power	夹持力应大于 0.5N The clamp-holding force shall be greater than 0.5N	合格 Qualified
	2.7 消毒钳 唇齿咬合性 Sterilizing forceps occlusion	消毒钳唇齿咬合性应打开自如。见附页 The occlusion of the sterilizing forceps should be opened freely. See the attached page	/
	2.8-2.13 外购配件要求 Requirements for outsourcing accessories	见附页 See the attached page	合格 Qualified
生物 biology	2.14 无菌 Sterile	产品应经过确认过的灭菌过程后, 应无菌。 The product shall be sterile after the confirmed sterilization process.	合格 Qualified
化学 chemistry	2.15 环氧乙烷残留量 Ethylene oxide residue amount	产品须经过环氧乙烷灭菌, 环氧乙烷的残留量应小于或等于 10mg/kg。The product must be sterilized with ethylene oxide, and the residual amount of ethylene oxide should be less than or equal to 10mg / kg.	合格 Qualified
结论 Conclusion	按湘械注准 20182640083 一次性使用换药包技术要求进行检测, 结果符合标准要求。The test was conducted according to the technical requirements of 20182640083, and the results meet the standard requirements. (质管部盖章 Seal of quality control department) 签发日期 Issue date: 2023/01/11		

Inspector:

Reviewer:

Check:

配置 Content:

序号/NO	产品名称 Product Name	规格型号 Specification	备注 Memo
1	一次性使用托盘 Disposable tray	19×10	外购件 bought-in components
2	一次性使用敷料镊子 Disposable dressing forceps	直 Straight	外购件 bought-in components
3	垫巾 Underpad	40×50cm	自产件 Self-produced parts
4	酒精棉球 Alcohol cotton ball	0.3g, 4粒 grains	自产件 Self-produced parts
5	医用纱布敷料 Medical gauze dressing	5×7×8层 layers	自产件 Self-produced parts
6	碘伏棉球 Iodine volt cotton ball	0.2g, 4粒 grains	自产件 Self-produced parts
7	Wrap	40×50cm	自产件 Self-produced parts

外购件 bought-in components :

检测项目 surveillance project	标准要求 Standard requirements	检验结果 Inspection result
一次性使用托盘 Disposable tray	塑料配件应光洁、色泽均匀，不应有毛刺、飞边和裂纹等现象。 Plastic accessories should be smooth, uniform color, there should not be burrs, flying edge and cracks.	合格 Qualified
一次性使用敷料 镊子 Disposable dressing forceps	夹持力应大于 0.5N The clamp-holding force shall be greater than 0.5N	合格 Qualified