

PRODUCTS SPECIFICATIONS 产品技术资料

Gauze Bandages 纱布绷带 (切边)

7mX14cm

Reference 产品代码

041304

MANUFACTURER

V-Medical

Applicable Standart: EN ISO 13485:2012 EN 14079

MDD 93/42/EEC amended by 2007/47 EN 11737-1

CE Classification IS

Notified Body: TUV RHEINLAND

SPECIFICATIONS

Gauze Bandages 7mX14cm

Reference:041304

Sterilization: sterilization

Indications: It is mainly used for fixing after operation or dressing.

Diameter: Φ4cm

Colour: White

Opened dimensions: 7m±20cmx14cm±0.5cm

Weight: ≥32g/m²

Weight/roll: 31.4g

CHARACTERISTICS

- Sinking time 沉没时间 ≤10sec
- Absorption capacity 吸水量 ≥10g/g
- pH pH 值 5.0~8.0
- Surface-active substances 表面活性物 ≤2mm
- Ether-soluble substances 醚中可溶物 <0.5%
- Water-soluble substances 水中可溶物 <0.5%
- Sulphated ash 硫酸盐灰分 <0.4%
- Fluorescence 荧光物 None, it displays only a slight
- Whiteness 白度 ≥80°
- Whiteness after sterile 灭菌后白度 ≥75°
- Extractable coloring matter 杂质色素 None
- Starch and dextrin 淀粉糊精 None
- Latex 乳胶 None
- Bisphenol A 双酚 A None
- Phthalates 邻苯二甲酸酯 None
- PVC 聚氯乙烯 None
- Animal or Biological product 动物或生物制品 None
- Drying loss 干燥失重 <8%
- Minimum mass 平方米克重 ≥32g/m²
- Minimum breaking load warp 经向最小断裂强度 ≥60N/5cm
- Minimum breaking load weft 纬向最小断裂强度 ≥45N/5cm
- Contents 成分 100% cotton
- Before sterilization Bacteria and fungi 灭菌前含菌量 less then 100cfu/g
- After sterilization Bacteria and fungi 灭菌后含菌量 None

QA Manager	Name: Yang Hao	Signature:	Date: 2022/04/13
Sales Manager	Name: Lora	Signature:	Date: 2022/04/13
General Manager	Name: Liu Tao	Signature:	Date: 2022/04/13

	Hubei V-medical Products Co.,Ltd 湖北唯美医疗用品有限公司 Products Specifications file 产品技术文件	Date 日期: 2022/04/13
		Rev 版本: A/0
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Bioburden 微生物水平	
Microbiological status 微生物要求	Max. 100 aerobic bacteria and fungi/g Max. 10 Enterobacteriaceae and other gramnegative bacteria/g No Pseudomonas aeruginosa/g No Staphylococcus aureus/g
Sterilization 灭菌	
Sterile 无菌	Yes 是
Sterilization method 灭菌方式	Sterile by EO 环氧乙烷灭菌
Packaging 包装	
Product packing 产品包装	1 roll/pouch 75pouches/carton 1 卷/袋, 75 袋/箱 carton size 箱规:38*28.8*33.5CM
Packing weight 包装重量	34g±2g
Paper 纸	White medical paper, 60 g/m ² , suitable for sterilization by ETO 白色医用纸张, 60 克/平方米, 适合 ETO 消毒
Laminate 膜	Polypropylene Film,thickness between 95~100 μm, suitable for sterilization by ETO 透明软膜, 膜厚在 95~100 μm, 适合 ETO 消毒
Size(LxWxH) 模具尺寸	8X26cm
Paper 纸	60g±0.5g/m ²
Laminate 膜	100g±10g/m ²
Welding width 封合宽度	≥5mm
Pads orientation in pack 产品放置方向	Flatwise 平放
Checking method-Pads/Pack 单包产品检验方式	1. Appearance test 外观检测: Visual inspection 目测 2.Specification and models 型号规格: Measured with ruler 直尺测量 3.Peel strength 剥离强度: ≥1.5N

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 V-MEDICAL Hubei V-Medical Products Co.,Ltd.	Hubei V-medical Products Co.,Ltd 湖北唯美医疗用品有限公司 Products Specifications file 产品技术文件		Date 日期: 2022/04/13
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30x15cm

 STERILE GAUZE BANDAGE 7M x 14CM REF 041304 Manufacturer: Hubei V-Medical Products Co.,Ltd. Made in China	STERILE GAUZE BANDAGE, 7M x 14CM REF 041304 QTY: 1roll/pouch, 75pouches/carton LOT 220314 2022-03-14 2027-02-13 N.W.: 2.5 KG G.W.: 3.0 KG MEAS:38x28.8x33.5cm      Made in China
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