



PRODUCTS SPECIFICATIONS 产品技术资料

Gauze Bandages 纱布绷带 (切边)

5mX10cm

Reference 产品代码

041302

MANUFACTURER

V-Medical

Applicable Standart: EN ISO 13485:2016 EN14079

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

CE Classification IS

Notified Body: TUV RHEINLAND

SPECIFICATIONS

Gauze Bandages 5mX10cm

Reference:041302

Sterilization: sterilization

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

Diameter: Φ 3.8cm

Colour: White

Opened dimensions: 5m $\pm$ 20cmx10cm $\pm$ 0.5cm

Weight: $\geq$ 32g/m²

Weight/piece: 16g

CHARACTERISTICS

- Sinking time 沉没时间 $\leq$ 10sec
- Absorption capacity 吸水量 $\geq$ 10g/g
- pH pH 值 5.0~8.0
- Surface-active substances 表面活性物 $\leq$ 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 $\geq$ 80°
- Whiteness after sterile 灭菌后白度 $\geq$ 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 $\geq$ 32g/m²
- Minimum breaking load warp 经向最小断裂强度 $\geq$ 60N/5cm
- Minimum breaking load weft 纬向最小断裂强度 $\geq$ 45N/5cm
- Contents 成分 100% cotton
- Before sterilization Bacteria and fungi 灭菌前含菌量 less than 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.		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
				Page 页码: 2/3
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 108pouches/carton 1 卷/袋, 108 袋/箱 箱规:38*28.8*33.5CM		
Packing weight 包装重量		19g±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		8X16cm		
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
			Rev 版本: A/0
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30x15cm

 STERILE GAUZE BANDAGE 5M x 10CM REF 041302 Manufacturer: Hubei V-Medical Products Co.,Ltd. Made in China	STERILE GAUZE BANDAGE,5M x 10CM REF 041302 QTY: 1roll /pouch, 108pouches/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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