



# PRODUCTS SPECIFICATIONS 产品技术资料

## Gauze Bandages 纱布绷带 (切边)

5mX10cm

Reference 产品代码

041301

### MANUFACTURER

V-Medical

Applicable Standart: EN ISO 13485:2016 EN14079:2003

MDR (EU) 2017/745

CE Classification I

Notified Body: TUV RHEINLAND

### SPECIFICATIONS

Gauze Bandages 5mX10cm

Reference: 041301

Sterilization: Non sterilization

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

Diameter:  $\Phi$  3.8cm

Colour: White

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

Weight:  $\geq$ 32g/m<sup>2</sup>

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<sup>o</sup>
- Whiteness after sterile 灭菌后白度 .....  $\geq$  75<sup>o</sup>
- 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/m<sup>2</sup>
- 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

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

 <b>V-MEDICAL</b> Hubei V-Medical Products Co., Ltd.	<b>Hubei V-medical Products Co.,Ltd</b> <b>湖北唯美医疗用品有限公司</b> <b>Products Specifications file</b> <b>产品技术文件</b>	Date 日期: 2022/04/13
		Rev 版本: A/0
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- Contents 成分 ..... 100% cotton
- Before sterilization Bacteria and fungi 灭菌前含菌量 ..... less than 100cfu/g

<b>Bioburden 微生物水平</b>	
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
<b>Sterilization 灭菌</b>	
Sterile 无菌	No Sterilization 不灭菌
Sterilization method 灭菌方式	No Sterilization 不灭菌
<b>Packaging 包装</b>	
Product packing 产品包装	10 rolls/pouch 300 rolls/carton 10 卷/袋 300 卷/外箱 箱规 39*39*31cm
Packing weight 包装重量	160g/pouches 160g/袋
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	Count 点数

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**湖北唯美医疗用品有限公司**  
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30x15cm



**NON-STERILE GAUZE BANDAGE**  
**5M x 10CM**



**REF** 041301

**Manufacturer: Hubei V-Medical Products Co.,Ltd.**  
**Made in China**

**NON-STERILE GAUZE BANDAGE, 5M x 10CM**

**REF** 041301

QTY: 10rolls/pouch, 300rolls/carton

**LOT** 220314  2022-03-14  2027-02-13

N.W.: 4.8 KG  
G.W.: 5.5 KG  
MEAS: 39x39x31cm



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