

 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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PRODUCTS SPECIFICATIONS 产品技术资料

Gauze Roll 纱布卷

90cmX1000m

Reference 产品代码

041305

MANUFACTURER

V-Medical
Applicable Standart: EN ISO 13485:2016 EN14079:2003
MDR (EU) 2017/745
CE Classification I
Notified Body: TUV RHEINLAND

SPECIFICATIONS

Gauze rolls: 90cmX1000m
Reference: 041305
Sterilization: Non sterilization
Indications:It is used for wound dressing, protection and cleaning of patients.
Colour: White
Opened dimensions: 90cm± 1.5cmx1000m
Weight: ≥32g/m²

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 ≥80⁰
- Whiteness after sterile 灭菌后白度 ≥75⁰
- 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
- Phtalates 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

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

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- Before sterilization Bacteria and fungi 灭菌前含菌量.....less then100cfu/g

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	No Sterilization 不灭菌
Sterilization method 灭菌方式	No Sterilization 不灭菌
Packaging 包装	
Product packing 产品包装	Plastic bag / woven bag 塑料袋+编织袋
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	According to the weight 称重点数

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30x15cm

 GAUZE ROLLS, 90CM x1000M REF 041305 Manufacturer: Hubei V-Medical Products Co.,Ltd. Made in China	GAUZE ROLLS , 90CM x1000M REF 041305 QTY: 1roll / plastic wrap bag +woven bag LOT 220314  2022-03-14  2027-02-13 N.W.: 5.0 KG G.W.: 5.5 KG MEAS: 39x39x31cm      Made in China
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