



File Name: Specification of Gauze Bandage		文件编号 File No.	
		版本状态 versions	2.0
编制 Drafted by	Shi Rongping	修改状态 modify	0.0
审核 Audited by	Liu Yan	生效日期 Effective date	
批准 Approved by	Yu Xiping	发放号 Release No.	

## 1 Scope

This document specifies the product specification and inspection requirement for Gauze Bandage supplied by Jianerkang Medical Co., Ltd.

## 2 Reference

- EN14079:2003 (Non-active medical devices. Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze)
- ISO 11607 (series, Packaging for Terminally Sterilized Medical Devices)
- EN 868-5 (Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods)
- ISO11135 (Sterilization of health-care products -- Ethylene oxide-- Requirements for the development, validation and routine control of a sterilization process for medical devices)

## 3 Product Specification

### 3.1 Intended Use:

Gauze Bandage main use is Provide binding force to wound dressings or limbs, play a role in bandaging and fixation.

### 3.2 Product list

No.	SKU	Product Description
1	203280	Gauze Bandage 10cmx5m non sterile 1roll/pack, 400packs/ case
2	203281	Gauze Bandage 10cmx5m sterile 1rolls/pouch, 400pouches/ case
3	203282	Gauze Bandage 14cmx7m non sterile 1roll/pack, 360packs/ case
4	203283	Gauze Bandage 14cmx7m sterile 1rolls/pouch, 300pouches/ case

### 3.3 Bill Of Material (BOM)

No.	Material	Description	Remark
1	Woven cloth	100% cotton, high hydrophilicity, non-toxic, non-allergic, non-inflamable bleaching agent. Odorless and tasteless. No loose threads.	





No.	Material	Description	Remark
		It meets EN14079 standard, binding canvas	
2	Inner paper	Medical Paper,40g/m <sup>2</sup>	
3	Package paper	Blue Paper,65g/m <sup>2</sup>	
4	Top web	Peelclean EO Paper,70g/m <sup>2</sup> Peelclean EO Paper,60g/m <sup>2</sup>	
5	Bottom film	PA+PE Film, Thickness 150um	
6	Poly bag	PE	
7	Case	5-ply corrugated cardboard, AB flute, 550g/m <sup>2</sup>	

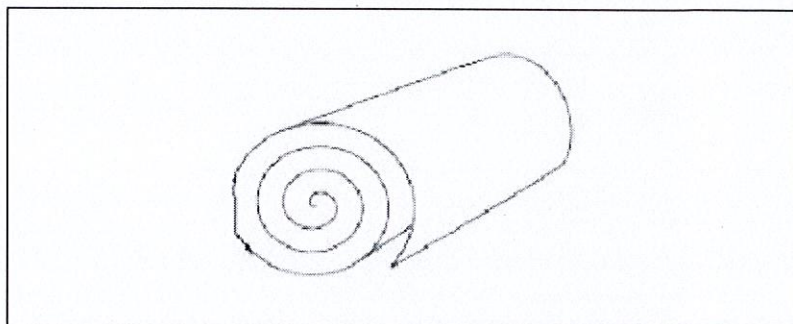
### 3.4 Dimension & Weight

SKU	Thread Count	Warp×weft density	Density (g/m <sup>2</sup> )	Width (cm)	Stretched Length (cm)	Roll Diameter (cm)	Roll weight (g)
203280	40s	30×26	32	10	500	2.5±0.5	16
203281	40s	30×26	32	10	500	2.5±0.5	16
203282	40s	30×26	32	14	700	3.3±0.5	31.36
203283	40s	30×26	32	14	700	3.3±0.5	31.36

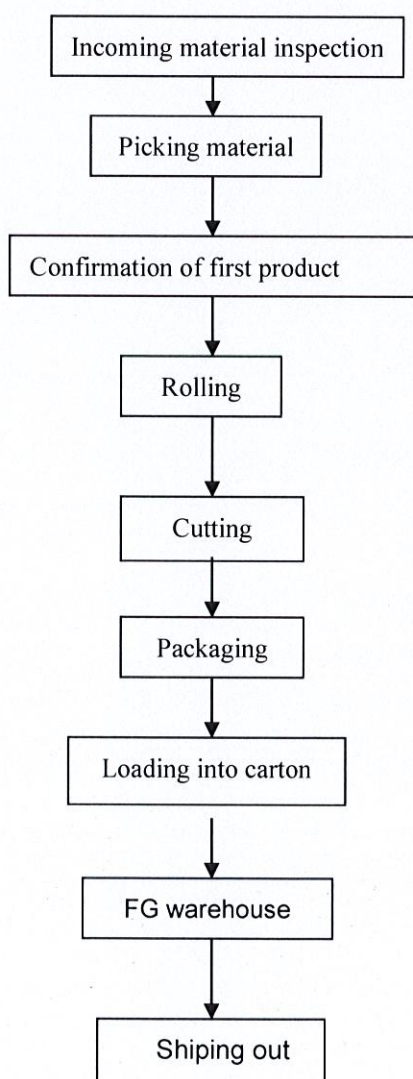
### 3.5 Packing configuration

Item No.	Packing		Packing Type and Dimension (cm)	Case Dimension L x W x H (cm) ±1 cm	G.W./Case (KGS)
	RL/pk	Pk/Cs			
203280	1	400	Packed with each roll	57x22x44	7.9
203281	1	400	Packed with blister pouchr per roll	41x31x31	8.1
203282	1	360	Packed with each roll	57x33x44	12.7
203283	1	300	Packed with blister pouchr per roll	44x35x35	10.9

### 3.6 Folding diagram



### 3.7 Manufacturing Process Flow Diagram







### 3.8 Shelf Life:

5years

### 3.9 Storage and Handling Requirement:

Store in cool and dry place, and free from direct sunlight.

## 4 REVISION HISTORY

Revision	Change Description	Issue Date
1.0	New issue	

*Geoff*  
健尔康医疗科技股份有限公司  
JIANERKANG MEDICAL CO., LTD