



File Name: Specification of Gauze Bandage		文件编号 File No.	1
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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, 960packs/ case
2	203281	Gauze Bandage 10cmx5m sterile 1rolls/pouch, 500pouches/ case
3	203282	Gauze Bandage 14cmx7m non sterile 1roll/pack, 480packs/ 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
		Binding canvas, 32g/m ² It meets EN14079 standard	
2	Inner paper	Medical Paper,40g/m ²	
3	Top web	Peelclean EO Paper,70g/m ² Peelclean EO Paper,60g/m ²	
4	Bottom film	PA+PE Film, Thickness 150um	
5	Poly bag	PE	
6	Case	5-ply corrugated cardboard, AB flute, 550g/m ²	

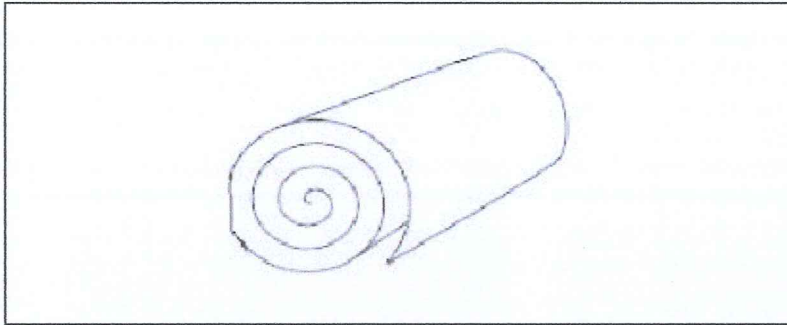
3.4 Dimension & Weight

SKU	Thread Count	Threads/cm ²	Density (g/m ²)	Width (cm)	Length (cm)	Roll Diameter (cm)	Roll weight (g)
203280	40s×40s	22	32	10	500	2.5±0.5	16
203281	40s×40s	22	32	10	500	2.5±0.5	16
203282	40s×40s	22	32	14	700	3.3±0.5	31.36
203283	40s×40s	22	32	14	700	3.3±0.5	31.36

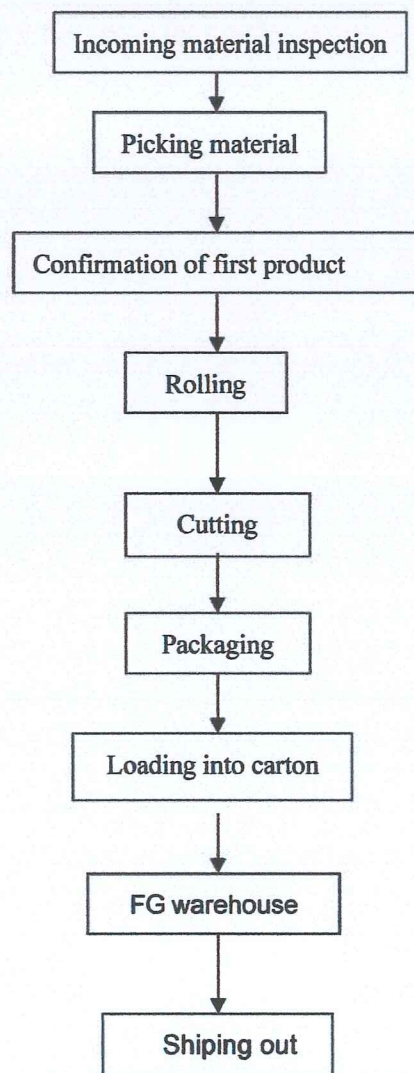
3.5 Packing configuration

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	960	Packed with each roll	52x32x50	17.0
203281	1	500	Packed with blister pouchr per roll	44x35x35	9.5
203282	1	480	Packed with each roll	58x42x42	17.0
203283	1	300	Packed with blister pouchr per roll	52x27x27	11.0

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	

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