



File Name: Specification of Gauze Roll		File No.	
		Versions	1.0
Drafted by	Shi Rongping	Modify	0.0
Audited by	Liu Yan	Effective date	
Approved by	Yu Xiping	Release No.	

1 Scope

This document specifies the product specification and inspection requirement for Gauze Roll 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 roll main use is absorbing blood and exudates on the wounds and cleaning it before medical treatments.

3.2 Product list

No.	SKU	Product Description
1	201177	Gauze roll 90cmX10m, 4ply, non sterile, 50rolls/ carton
2	201187	Gauze roll 90cmX100m, 4ply, non sterile, 12rolls/ carton

3.3 Bill Of Material (BOM)

No.	Material	Description	Remark
1	Woven cloth	100% cotton, high hydrophilicity, non-toxic, non-allergic, non-inflammable bleaching agent. Odorless and tasteless. No loose threads. It meets EN14079. Binding canvas.	
2	Inner paper	Medical Paper,40g/m ²	



No.	Material	Description	Remark
3	Package paper	Medical Paper,55g/m ²	
4	Poly bag	PE	
5	Case	5-ply corrugated cardboard, AB flute, 550g/m ²	

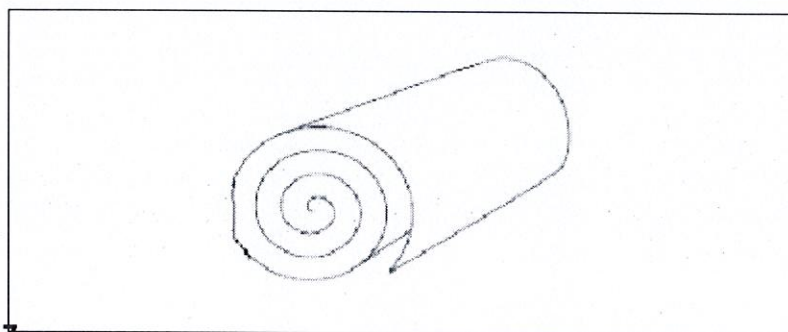
3.4 Dimension & Weight

SKU	Thread Count	Warp×weft density	Density (g/m ²)	Width (cm)	Stretched Length (m)	Roll Diameter (cm)	Roll weight (g)
201177	40s	30×26	32	90	10	7+/-0.5	288
201187	40s	30×26	32	90	100	23+/-1	2880

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			
201177	1	50	Packed with blue paper per roll	46x36x36	16.4
201187	1	12	Packed with blue paper per roll	70x47x46	36.5

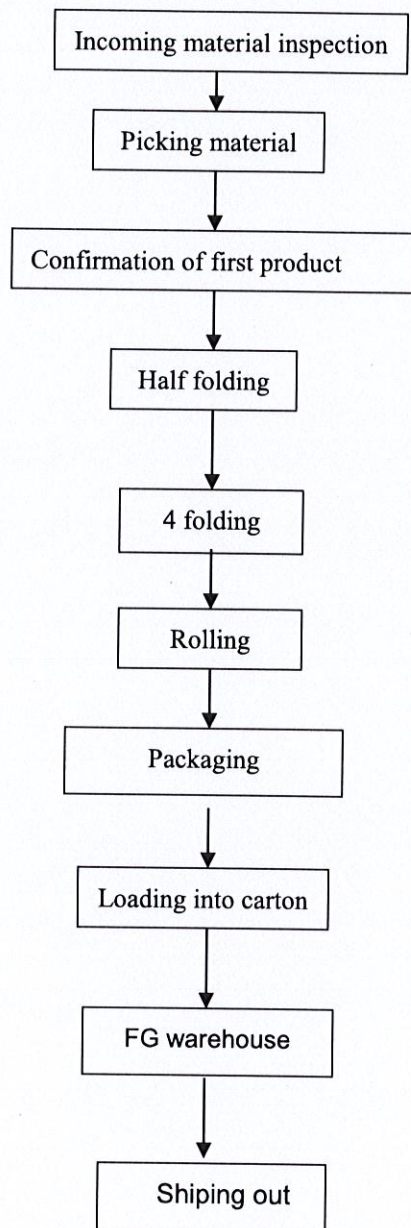
3.6 Folding diagram



3.7



3.8 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
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