



File Name: Specification of the Absorbent Cotton Wool		File No.	
		Versions	1.0
Drafted by	Shi Rongping	Modify	0.0
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Approved by	Yu Xiping	Release No.	

1 Scope

This document specifies the product specification and inspection requirement for Absorbent Cotton wool 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:

Absorbent cotton wool are used to clean wounds, absorption of exudates and isolate wounds.

3.2 Product list

No.	SKU	Product Description
1	202016	Absorbent Cotton Wool 100g/roll, non sterile, 100rolls/ case
2	202017	Absorbent Cotton Wool 250g/roll, non sterile, 50rolls/ case
2	202018	Absorbent Cotton Wool 50g/roll, non sterile, 200rolls/ case

3.3 Bill Of Material (BOM)

No.	Material	Description	Remark
1	Woven cloth	100% cotton Well-balanced, uniform consistency, long cotton wool that forms strips or white masses, light, odorless and tasteless,	



No.	Material	Description	Remark
		without reducing substances, without bleaching agents, without acidity / alkalinity, no impurities, hydrophilies under 10sec	
2	Inner paper	Medical Paper,40g/m ² or milk PE bag	
3	Package paper	Medical Paper,55g/m ²	
4	Package bag	Milk PE bag	
5	Poly bag	PE	
6	Case	5-ply corrugated cardboard, AB flute, 550g/m ²	

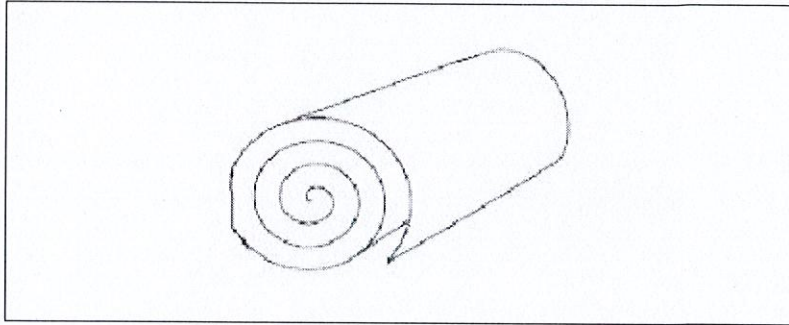
3.4 Dimension & Weight

SKU	Width(cm)	Roll Diameter (cm)	Roll weight (g)
202016	13	6.2±0.5	100
202017	15.5	9±0.5	250
202018	9	5±0.5	50

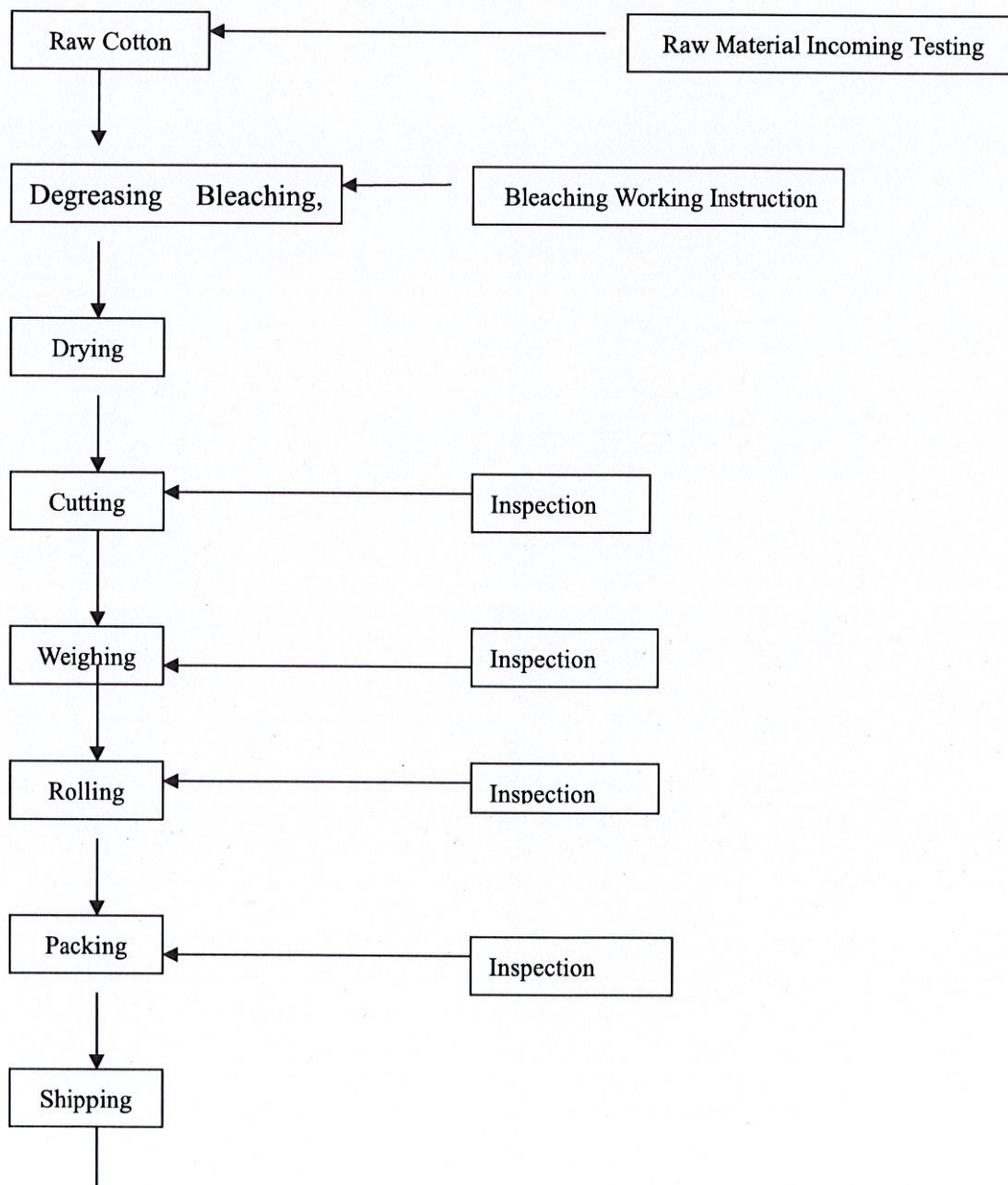
3.5 Packing configuration

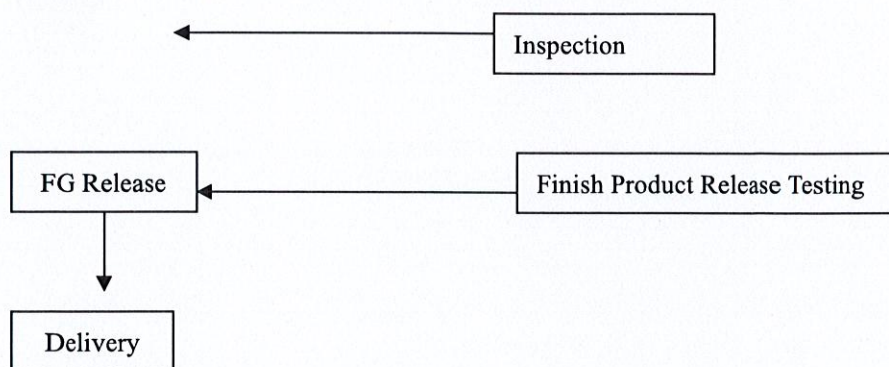
Item No.	Packing		Packing Type	Case Dimension L x W x H (cm) ± 1 cm	G.W./Case (KGS)
	RL/pk	Pk/Cs			
202016	1	100	Packed with blue paper each roll	62x31x28	12
202017	1	50	Packed with blue paper each roll	45x32x45	14
202018	1	200	Packed with blue paper each roll	51x26x38	11.5

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
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