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|-------------------------------------------|--------------|---------------------|-----|
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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, 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><br>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,<br>550g/m <sup>2</sup>                   |        |

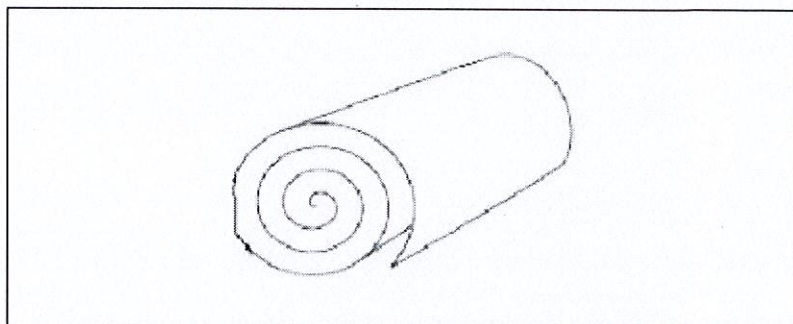
### 3.4 Dimension & Weight

| 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           |

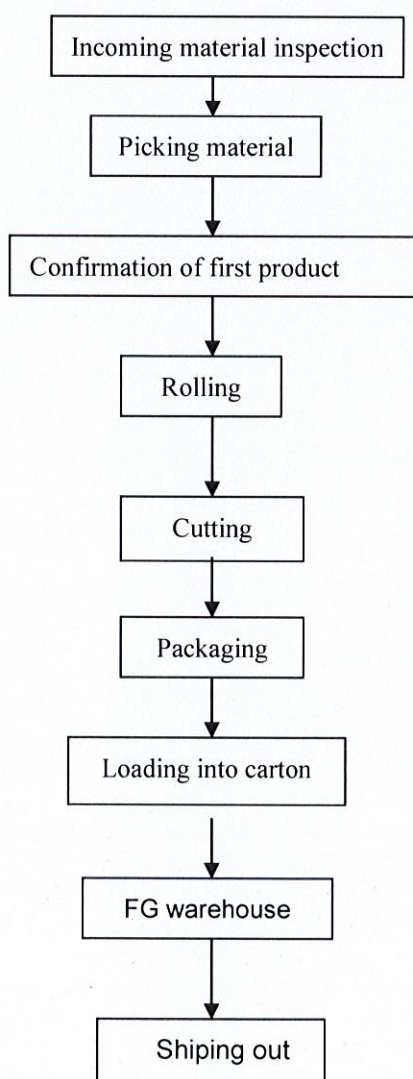
### 3.5 Packing configuration

| 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          |            |

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