



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 002037 0009 Rev. 01**

**Manufacturer:** **Allmed Medical Products Co., Ltd**  
No.18 Qixing Road, Majiadian Town  
443200 Zhijiang City, Hubei Province  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, GERMANY

**Product Category(ies):** Non-woven Swabs, Gauze Swabs,  
Sterile Paraffin Gauze Dressing,  
Sterile and Non-sterile Lap Sponges  
(with or without x-ray thread),  
Sterile and Non-sterile Gauze Ball  
(with or without x-ray thread),  
Sterile and Non-sterile Non-woven Ball  
(with or without x-ray thread),  
Sterile and Non-sterile Non-woven Swabs  
(with or without x-ray thread),  
Sterile and Non-sterile Gauze Swabs  
(with or without x-ray thread),  
Sterile and Non-sterile Cutting Gauze  
(with or without x-ray thread),  
Sterile and Non-sterile Zig Zag (folded) Gauze  
(with or without x-ray thread),  
Sterile and Non-sterile OR Towel  
(with or without X-Ray Thread) ,  
Medical Kits, Woundhook Covers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** SH19256EXT01  
**Valid from:** 2019-09-09  
**Valid until:** 2024-05-26  
**Date,** 2019-06-21

Stefan Preiß  
Head of Certification/Notified Body

ZERTIFIKAT ♦ CERTIFICATE ♦ CERTIFICADO ♦ CERTIFIKAT ♦ 認證證書 ♦ CERTIFICATE ♦ CERTIFICATE



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# EC Certificate

Production Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

**No. G2 002037 0009 Rev. 01**

## Facility(ies):

Allmed Medical Products Co., Ltd  
No.18 Qixing Road, Majiadian Town, 443200  
Zhijiang City, Hubei Province, PEOPLE'S  
REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
No. 180 Gong Yuan Road, Majiadian Town, 443200  
Zhijiang City, Hubei Province, PEOPLE'S  
REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
No. 76, You Yi Road, Majiadian Town, 443200  
Zhijiang City, Hubei Province, PEOPLE'S  
REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
No. 99, Jin Shan Road, Majiadian Town, 443200  
Zhijiang City, Hubei Province, PEOPLE'S  
REPUBLIC OF CHINA

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# Certificate

No. Q5 002037 0008 Rev. 01

**Holder of Certificate:** **Allmed Medical Products Co., Ltd**  
 No.18 Qixing Road, Majiadian Town  
 443200 Zhijiang City, Hubei Province  
 PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:**

Design and Development, Production and Distribution of Gauze Swabs, Non-Woven Swabs, Drain Sponges, Post-Op Sponges, ABD Pads, Fluffy Gauze Swabs, Fluffy Gauze Bandages, Cotton-Filled Exodontia Sponges, Gauze Balls, Non-Woven Balls, Non-Stick Pads, Eye Pads, Triangular Bandages, Sterile Paraffin Gauze Dressing, Adhesive Bandage, Sterile and Non-sterile Lap Sponges (with or without X-Ray Thread), Sterile and Non-sterile Gauze Swabs (with or without X-Ray Thread), Sterile and Non-sterile Non-woven Swabs (with or without X-Ray Thread), Sterile and Non-sterile Gauze Ball (with or without X-Ray Thread), Sterile and Non-sterile Non-woven Ball (with or without X-Ray Thread), Elastic Bandages, Sterile and Non-sterile OR Towel (with or without X-Ray Thread), Skin marker, Neurological Surgery Slices, Gauze Packing Strip, Breast Pad, Sterile Bowl, Maternity Pad, Compressed Bandage, Absorbent Cotton Roll, Adhesive Tape, Adhesive Dressing, Medical Kits, Woundhook Covers, Tubular Bandages, Tongue Depressors and Cotton Applicators

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

<b>Report No.:</b>	SH1925619
<b>Valid from:</b>	2019-09-01
<b>Valid until:</b>	2022-08-31

**Date,** 2019-08-07

Stefan Preiß  
 Head of Certification/Notified Body

# Certificate

No. Q5 002037 0008 Rev. 01

## Applied Standard(s):

EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

## Facility(ies):

Allmed Medical Products Co., Ltd  
No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei  
Province, PEOPLE'S REPUBLIC OF CHINA

Allmed Medical Products Co., Ltd.  
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Hubei Province, PEOPLE'S REPUBLIC OF CHINA

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## Gauze Roll

**Non-Sterile**  
**With / Without X-ray thread**

### Field of Application

- Cleanse and compress wound directly
- Hold the dressing securely in place without slipping

### Properties

- Made of 100% bleached cotton gauze
- Durable, hold the dressing securely in place
- Easy to cut to any shapes and sizes
- Super softness and patient comfort
- Highly absorbent
- Low linting
- Quality: EN 14079

### Description

Catalogue No.	Size	Ply	Packaging	Thread
AM-GR90-90	90cm×90M	4 Ply	1 roll/sleeve	15 Thread
AM-GR90-90-1	90cm×90M	4 Ply	1 roll/sleeve	13 Light
AM-GR90-90-24A	90cmx90M	4 Ply	1 roll/sleeve	24 a



## Gauze Bandage

**Non-Sterile / Sterile**

### Field of Application

- Secure dressings, splints or provide mild compression and support
- Secondary wounds dressing

### Properties

- Soft and comfortable
- Low linting
- High absorbency
- Easy to cut
- Hypoallergenic and good absorbance capacity
- Quality: EN 14079



### Description

Catalogue No.	Size	Packaging
AM-GB05450	5cmx4.5M	1 roll/pack
AM-GB07450	7.5cmx4.5M	1 roll/pack
AM-GB10450	10cmx4.5M	1 roll/pack
AM-GB15450	15cmx4.5M	1 roll/pack
AM-GB10500	10cmx5M	1 roll/pack
AM-GB14700	14cmx7M	1 roll/pack
AM-GB10500-S	10cmx5M	1 roll/pack
AM-GB14700-S	14cmx7M	1 roll/pack



## 检测报告 Test Report

报告编号 Report No: TC2109110009

样品信息 Sample information:

样品名称 Sample name	脱脂纱布	产品号/料号 Product code	9990
生产单位 Manufactory	国际业务事业群事业 1 部脱漂车间	订单号 Order #	4545253134
规格 Specification	40Sx40S/30x30-124cm $\geq$ 32g/m <sup>2</sup>	批号 Lot #	21090917-1514-10
测试方法 Test method	EN 14079:2003	测试周期 Testing period	2021-11-06 ~ 2021-11-07

检测结果 Test Result:

项目 Item	单位 Unit	标准 Standard	结果 Results	结论 Conclusion
水中可溶物 Water-soluble substances	%	总量不大于 0.50% No more than 0.50%.	0.20	OK
醚中可溶物 Ether-soluble substances	%	总量不大于 0.50% No more than 0.50%.	0.16	OK
硫酸盐灰分 Sulphated ash	%	总量不大于 0.40% No more than 0.40%.	0.18	OK
淀粉和糊精 Starch and dextrin	\	溶液不应显蓝色、紫色、淡红色或淡棕色。 Solution shall not show any blue,violet,red dish or brownish colour.	Complies	OK
酸碱度 Acidity and alkalinity	\	两者均不得显粉红色。 No pink color develops in either portion.	Complies	OK
可浸提的着色物质 Extractable colouring matter	\	滤液的颜色应不深于对照液 Y5 或 GY6 或蓝色对照溶液。 Liquid obtained shall not be more intensely coloured than reference solution Y5,GY6 or blue reference solution.	Complies	OK
外来纤维 Foreign fibres	\	可以偶尔有少量孤立的外来纤维存在。 A few isolated foreign fibres may also be present.	Complies	OK
纤维鉴别 Fibre Identification	\	棉纤维应符合鉴别试验 A,B 和 C 的要求。 Cotton fibres shall conform to the IDENT tests A, B and C.	Complies	OK
干燥失重 Loss by Drying	%	$\leq$ 8.0 No more than 8.0	5.40	OK

备注 Remarks:

接收标准: EN14079:2003

结论 Conclusion:

Pass



编制人/日期: 刘小奇 2021.11.07  
Edited by/ Date:

审核人/日期: 杨玉蓉 2021.11.08  
Checked by/Date:

批准人/日期: 杨梦菊 2021.11.08  
Approved by/Date:

本报告仅对检测样品负责 This report is only responsible for the provided sample.

表格编号 Form#: LTR-001-001  
表格批准人 Approved By: 戴虹梅

执行日期 Effective Date: 2021-07-02  
相关文件号#: N/A



# ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200

Zhijiang City, Hubei province, (China)

## GAUZE BANDAGE

### TECHNICAL PROPERTIES

Content: 100% bleached cotton yarn;

Weft-Warp String number: 40Sx40S/30x30-124cm,  $\geq 32\text{g/m}^2$ ;

Width: 10cm, 14cm, other sizes available;

Length: Can be cut as required;

Shelf life: 5 years

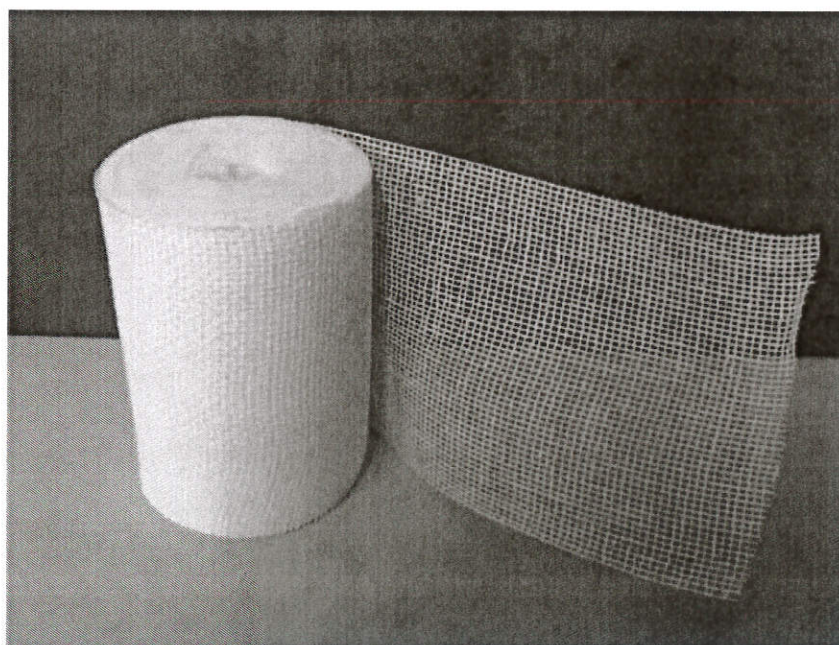
*For and on behalf of*  
**ALLMED MEDICAL PRODUCTS CO., LIMITED**

*Susan Liao*

.....  
*Authorized Signature(s)*

### Non-Sterile Hydrophilic Gauze Bandage

REF Code	SIZE	BOX in (Roll)	Box Size (cm)
AM-GB10500	10cm x 5m	540	45 x 36.5 x 38 cm
AM-GB14700	14cm x 7m	360	51 x 48.5 x 31 cm



### Intended use:

This device is intended to be used for fixation of dressings or tampon on the wound, with protection and barrier function (mechanical) of the injured skin. It provides mild compression and support. MD Class I according to Regulation (EU) 2017/745 of the European Parliament and Council.

**Product standards:** In compliance with EN 14079.

**Certificates:** CE, ISO13485.

**Labeling:** in accordance with Chapter III (23) of Annex I of Regulation 2017/745 of the European Commission.



## ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200

Zhijiang City, Hubei province, (China)

### Cautions:

- Read instructions before use.
- Before usage check the packing completeness, the LOT number and expiry date.
- Use only if package is undamaged and validity not expired;
- For single use.
- Destroy after use.

### Properties:

- Non-toxic;
- Hypoallergenic;
- Non-inflammable;
- PHT and DEHP free;
- Latex free;
- Soft and comfortable;
- Low linting;
- High absorbance capacity;
- Easy to cut;
- Free from loose wires;
- Non-Sterile unit packages.

*For and on behalf of*

ALLMED MEDICAL PRODUCTS CO., LIMITED

*Susan Liao*

.....  
*Authorized Signature(s)*

### Instructions for use:

1. Select the appropriate Gauze Bandage size for your procedure.
2. Examine individual package for integrity of packaging prior to use. Do not use if packaging is broken.
3. Wash hands. (Wear gloves where necessary).
4. Before usage, open the unit package.
5. Apply the bandage in accordance with your facility's protocol.
6. Support the injured area while bandaging (if necessary).
7. Immediately dispose of after single use.

### Packing:

- each bandage is rolled and individually packed
- then is packed in strong export carton

### Storage:

Protect from sunlight, extreme humidity and heat sources. Not store with organic or chemical solvents. Not store with corrosive gases. Store in dry, cool, good ventilated and clean room, where temperatures between 10°C and 40°C and relative humidity between 30% and 60% are recommended



ALLMED MEDICAL PRODUCTS CO.,LTD.

Address: No.18 Qixing Road, Majiadian Town,443200, Zhijiang City, Hubei province, China.





# ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200  
Zhijiang City, Hubei province, (China)

## STERILE GAUZE BANDAGE

### TECHNICAL PROPERTIES

Content: 100% bleached cotton yarn;

Weft-Warp String number: 40Sx40S/30x30-124cm,  $\geq 32\text{g/m}^2$ ;

Width: 10cm, 14cm, other sizes available;

Length: Can be cut as required;

Shelf life: 5 years

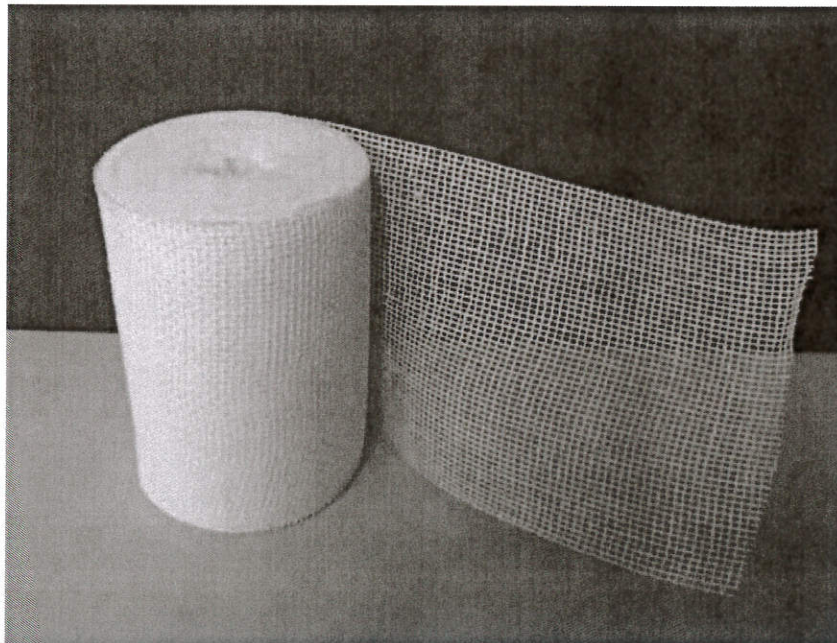
*For and on behalf of*  
ALLMED MEDICAL PRODUCTS CO., LIMITED

*Susan Liao*

*Authorized Signature(s)*

### Sterile Hydrophilic Gauze Bandage

REF Code	SIZE	BOX in (Roll)	Box Size (cm)
AM-GB10500-S	10cm x 5m	150	37x 28.5 x 26 cm
AM-GB14700-S	14cm x 7m	100	33 x 31 x 31 cm





## ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200

Zhijiang City, Hubei province, (China)

### Intended use:

This device is intended to be used for fixation of dressings or tampon on the wound, with protection and barrier function (mechanical) of the injured skin. It provides mild compression and support. MD Class I-sterile according to Directive (EU) 93/42/ EEC (DL145/2009).

**Product standards:** In compliance with EN 14079; EN ISO 11737-2.

**Certificates:** CE, ISO13485.

**Labeling:** in accordance with according to Directive (EU) 93/42/ EEC (DL145/2009).

### Cautions:

- Read instructions before use.
- Before usage check the sterility validity, packing completeness, the LOT number and expiry date.
- Use only if package is undamaged and validity not expired.
- For single use. The re-sterilization is prohibited.
- Destroy after use.

### Properties:

- Non-toxic;
- Hypoallergenic;
- Non-inflammable;
- PHT and DEHP free;
- Latex free;
- Soft and comfortable;
- Low linting;
- High absorbance capacity;
- Easy to cut;
- Free from loose wires;
- Sterile unit packages.

### Instructions for use:

1. Select the appropriate Gauze Bandage size for your procedure.
2. Examine individual package for integrity of packaging prior to use. Do not use if packaging is broken.
3. Wash hands. (Wear gloves where necessary).
4. Before usage, open aseptically the unit package.
5. Apply the bandage aseptically in accordance with your facility's protocol.
6. Support the injured area while bandaging (if necessary).
7. Immediately dispose of after single use.

### Packing:

- each bandage is rolled and individually packed
- then is packed in strong export carton

For and on behalf of  
ALLMED MEDICAL PRODUCTS CO., LIMITED

*Susan Liao*

Authorized Signature(s)



**ALLMED MEDICAL PRODUCTS CO.,LTD.**

No.18 Qixing Road, Majiadian Town,443200

Zhijiang City, Hubei province, (China)

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**Storage:**

Protect from sunlight, extreme humidity and heat sources. Not store with organic or chemical solvents. Not store with corrosive gases. Store in dry, cool, good ventilated and clean room, where temperatures between 10°C and 40°C and relative humidity between 30% and 60% are recommended



**ALLMED MEDICAL PRODUCTS CO.,LTD.**

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*Susan Liao*

.....  
*Authorized Signature(s)*



# ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200

Zhijiang City, Hubei province, (China)

## GAUZE ROLL

### TECHNICAL PROPERTIES

Content: 100% bleached cotton yarn;

Weft-Warp String number: 40Sx40S/30x30-124cm,  $\geq 32\text{g/m}^2$ ;

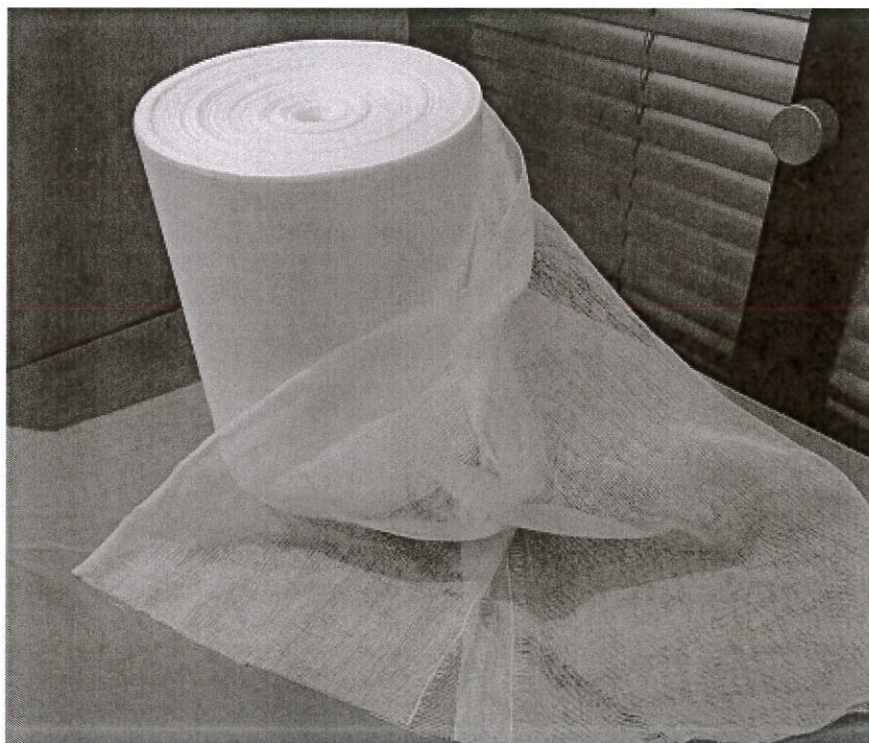
Width: 90 cm;

Length: 90 meters, Can be cut as required;

Shelf life: 5 years.

### Non-Sterile Hydrophilic Gauze Roll

REF Code	SIZE	BOX in (Roll)	Box Size (cm)
AM-GR90-90-24A	90cm x 90m	4	50 x 49.5 x 24cm



For and on behalf of  
ALLMED MEDICAL PRODUCTS CO., LIMITED

*Susan Liao*

Authorized Signature(s)



## ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200  
Zhijiang City, Hubei province, (China)

---

### **Intended use:**

This device is intended to be widely used in medical circle and other area for preparing of dressings or tampon with their further fixation on the wound, with protection and barrier function (mechanical) of the injured skin. MD Class I according to Regulation (EU) 2017/745 of the European Parliament and Council.

**Product standards:** In compliance with EN 14079.

**Certificates:** CE, ISO13485.

**Labeling:** in accordance with Chapter III (23) of Annex I of Regulation 2017/745 of the European Commission.

### **Cautions:**

- Read instructions before use.
- Before usage check the packing completeness, the LOT number and expiry date.
- Use only if package is undamaged and validity not expired;
- For single use.
- Destroy after use.

### **Properties:**

- Non-toxic;
- Hypoallergenic;
- Non-inflammable;
- PHT and DEHP free;
- Latex free;
- Durable, hold the dressing securely in place;
- Easy to cut to any shapes and sizes;
- Super softness and patient comfort;
- Highly absorbent;
- Low linting;
- Free from loose wires;
- Non-Sterile unit packages.

*For and on behalf of*  
ALLMED MEDICAL PRODUCTS CO., LIMITED

*Susan Liao*

.....  
*Authorized Signature(s)*



## ALLMED MEDICAL PRODUCTS CO.,LTD.

No.18 Qixing Road, Majiadian Town,443200

Zhijiang City, Hubei province, (China)

### Instructions for use:

1. Examine individual package of a roll for integrity of packaging prior to use. Do not use if packaging is broken.
2. Wash hands. (Wear gloves where necessary).
3. Before usage, open the roll package.
4. Cut the appropriate Gauze Material size for your procedure.
5. Apply the bandage in accordance with your facility's protocol.
6. Support the injured area while bandaging (if necessary).
7. Immediately dispose of after single use.

### Packing:

- each gauze roll is individually packed
- then is packed in strong export carton

### Storage:

Protect from sunlight, extreme humidity and heat sources. Not store with organic or chemical solvents. Not store with corrosive gases. Store in dry, cool, good ventilated and clean room, where temperatures between 10°C and 40°C and relative humidity between 30% and 60% are recommended. Once the package is opened, store the remaining roll isolated in clean environment in compliance with conditions mentioned above.



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