

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





奥美医疗
ALLMED MEDICAL

STERILE GAUZE BANDAGE

TECHNICAL PROPERTIES

Content: 100% bleached cotton yarn;

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

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

Length: Can be cut as required;

Shelf life: 5 years

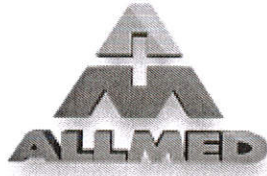
For and on behalf of
ALLMED MEDICAL PRODUCTS CO., LIMITED

Sterile Hydrophilic Gauze Bandage

Susan Liao

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





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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.

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

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.

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).



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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

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: 19F, Block A, Taurus Plaza, No.8, Taoyuan Rd., Nanshan District, Shenzhen City, P.R.C

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

Susan Liao

.....
Authorized Signature(s)



奥美医疗用品股份有限公司检测中心
ALLMED MEDICAL PRODUCT Co., Ltd, TESTING CENTER

检测报告
Test Report

报告编号 Report No: TC2203030035

样品信息 Sample information:

样品名称 Sample name	纱布分切卷	产品号/料号 Product code	N/A
生产单位 Manufactory	国际业务事业群事业 1 部脱漂车间 MA1031E	订 单 号 Order #	N/A
规格 Specification	40Sx40S/30x30-187cm-18X-3 幅 (155 进*2+157 进)	批 号 Lot #	22022513-8713-1
测试方法 Test method	EN14079:2003	测试周期 Testing period	2022-03-07 ~ 2022-03-08

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%.	0.26	OK
醚中可溶物 Ether-soluble substances	%	总量不大于 0.50% No more than 0.50%.	0.20	OK
硫酸盐灰分 Sulphated ash	%	总量不大于 0.40% No more than 0.40%.	0.19	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

备注 Remarks:

接收标准: EN14079:2003

结论 Conclusion:

The inspection results for the inspected items are in accordance with the relative specifications in the inspection reference, and the corresponding performance of the inspected samples is qualified.



编制人/日期: 刘奇 2022.03.08
Edited by/ Date:

审核人/日期: 杨玉莹 2022.03.09
Checked by/Date:

批准人/日期: 杨梦菊 2022.03.09
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

Pouch dimensions: 107x125mm
color: Pantone Green







Gauze Bandage
10cm*5M, 1 roll/pack
REF AM-GB10500S

LOT

21090917-1514-10










2026-12-20




2021-12-20

Store in cool and dry place.



STERILE

Made in China




Allmed Medical Products Co., LTD.
No. 180 Gong Yuan Road, Majiadian Town
443200 Zhijiang City - Hubei Province - China.
Shanghai International Holding Corp. GmbH (Europe)
Eiffelstrasse 80 - 20537 Hamburg - Germany
Tel : 0049 040 255 750

EC

REP

Pouch dimensions: 107x125mm
color: Pantone Green







Gauze Bandage
14cm*7M, 1 roll/pack
REF AM-GB14700S

LOT

21090917-1514-10











2026-12-20




2021-12-20

Store in cool and dry place.



Made in China



Allmed Medical Products Co., LTD.
No. 180 Gong Yuan Road, Majiadian Town
443200 Zhijiang City - Hubei Province - China.
Shanghai International Holding Corp. GmbH (Europe)
Eiffelstrasse 80 - 20537 Hamburg - Germany
Tel : 0049 040 255 750

EC

REP



Certificate

No. Q5 002037 0008 Rev. 04

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
Non-active Medical Devices
(For Details, Please See Last Page)

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 002037 0008 Rev. 04

Report No.: SH2225601

Valid from: 2022-12-28

Valid until: 2025-08-31

Date, 2022-12-28

Christoph Dicks
Head of Certification/Notified Body

No. Q5 002037 0008 Rev. 04

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

Allmed Medical Products Co., Ltd

No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei
Province, PEOPLE'S REPUBLIC OF CHINA

Design, Development, 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 Nonsterile Gauze Swabs
(with or without X-Ray Thread),
Sterile and Non-sterile Nonwoven 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 Medical OR Towel
(with or without X-Ray Thread),
Surgical skin marker, Medical Neuro Sponges,
Gauze Packing Strip, Sterile Medical Bowl,
Compressed Bandage, Absorbent Cotton Roll,
Medical Adhesive Tape, Adhesive Dressing,
SURGICAL PROCEDURAL KITS
(EXCLUDING SURGICAL INSTRUMENT KITS),
DRESSING AND ASSISTANCE KITS,
Woundhook Covers, Tubular Bandages,
Tongue Depressors and Cotton Applicators,
Medical Face Mask, Medical Scissors,
Medical Measuring cup/bowl, Surgical drape,
Surgical gown, Medical Isolation gown,
Medical protective clothing

No. Q5 002037 0008 Rev. 04

Allmed Medical Products Co., Ltd.

Production and Distribution of
Gauze 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,
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 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 Medical OR Towel
(with or without X-Ray Thread),
Medical Neuro Sponges,
Compressed Bandage, Gauze Packing Strip,
Absorbent Cotton Roll,
Woundhook Covers

TÜV®

Certificate

No. Q5 002037 0008 Rev. 04

Facility(ies):

Allmed Medical Products Co., Ltd.

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

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, 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 Medical OR Towel
(with or without X-Ray Thread),
Surgical skin marker, Medical Neuro Sponges,
Sterile Medical Bowl, Compressed Bandage,
Medical Adhesive Tape, Adhesive Dressing,
SURGICAL PROCEDURAL KITS
(EXCLUDING SURGICAL INSTRUMENT KITS),
DRESSING AND ASSISTANCE KITS,
Tubular Bandages,
Tongue Depressors and Cotton Applicators,
Medical Face Mask, Medical Scissors,
Medical Measuring cup/bowl,
Surgical drape, Surgical gown, Medical Isolation gown,
Medical protective clothing

No. Q5 002037 0008 Rev. 04

Allmed Medical (Hubei) Protective Products Co., Ltd.

Production and Distribution of Medical Face Mask, Surgical drape, Surgical gown, Medical Isolation gown, Medical protective clothing

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

Certificate

No. Q5 002037 0008 Rev. 04

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 Nonsterile Gauze Swabs
(with or without X-Ray Thread),
Sterile and Non-sterile Nonwoven 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 Medical OR Towel
(with or without X-Ray Thread),
Surgical skin marker, Medical Neuro Sponges,
Gauze Packing Strip, Sterile Medical Bowl,
Compressed Bandage, Absorbent Cotton Roll,
Medical Adhesive Tape, Adhesive Dressing,
SURGICAL PROCEDURAL KITS
(EXCLUDING SURGICAL INSTRUMENT KITS),
DRESSING AND ASSISTANCE KITS,
Woundhook Covers, Tubular Bandages,
Tongue Depressors and Cotton Applicators,
Medical Face Mask, Medical Scissors,
Medical Measuring cup/bowl, Surgical drape,
Surgical gown, Medical Isolation gown,
Medical protective clothing



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



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

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