





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

Christoph Dicks 2022-12-28 Date,

Head of Certification/Notified Body



No. Q5 002037 0008 Rev. 04

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Allmed Medical Products Co., Ltd Facility(ies):

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

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CERTIFICATE



Certificate

No. Q5 002037 0008 Rev. 04

Allmed Medical Products Co., Ltd. Facility(ies):

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

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

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Certificate

No. Q5 002037 0008 Rev. 04

Allmed Medical Products Co., Ltd. Facility(ies):

No. 76, You Yi 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, Eye Pads, 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 Mecical OR Towel

(with or without X-Ray Thread),

Surgical skin marker, Medical Neuro Sponges,

Sterile Medical Bowl, Compressed Bandage,

SURGICAL PROCEDURAL KITS

(EXCLUDING SURGICAL INSTRUMENT KITS),

DRESSING AND ASSISTANCE KITS, Tongue Depressors,

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

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

Facility(ies):

Allmed Medical Products Co., Ltd.-Jianli

No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County, 433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of sterile and non-sterile lap sponges (with or without x-ray thread), sterile and non-sterile Medical OR Towel (with or without x-ray thread)





No. Q5 002037 0008 Rev. 04

Facility(ies): Allmed Medical (Hubei) Protective Products Co.,

No. 29 Dong Hu Road, Majiadian Town, 443200 Zhijiang City,

Hubei, PEOPLE'S REPUBLIC OF CHINA

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





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





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

Shanghai International Holding Corp. GmbH (Europe) **EC-Representative:**

Eiffestraße 80, 20537 Hamburg, GERMANY

Non-woven Swabs, Gauze Swabs, Product Sterile Paraffin Gauze Dressing, Category(ies):

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.

SH19256EXT01 Report No.: 2019-09-09 Valid from:

Valid until: 2024-05-26

2019-06-21

Stefan Preiß

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Head of Certification/Notified Body

Page 1 of 2

Date,

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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







No. Q8 002037 0002 Rev. 03

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:



The Provision of ETO and Moist Heat Sterilization Scope of Certificate:

services for Medical Devices

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:Q8 002037 0002 Rev. 03

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. Q8 002037 0002 Rev. 03

EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Allmed Medical Products Co., Ltd Facility(ies):

No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City, Hubei

Province, PEOPLE'S REPUBLIC OF CHINA

Legal Entity with Management Oversight Responsibility for all

Quality Related Matters

Allmed Medical Products Co., Ltd.

No. 180 Gong Yuan Road, Majiadian Town, 443200 Zhijiang City,

Hubei Province, PEOPLE'S REPUBLIC OF CHINA

The Provision of Moist Heat Sterilization services for Medical

Devices

Allmed Medical Products Co., Ltd.

No. 76, You Yi Road, Majiadian Town, 443200 Zhijiang City, Hubei

Province, PEOPLE'S REPUBLIC OF CHINA

The Provision of Moist Heat Sterilization services for Medical

Devices

Allmed Medical Products Co., Ltd.

No. 99, Jin Shan Road, Majiadian Town, 443200 Zhijiang City,

Hubei Province, PEOPLE'S REPUBLIC OF CHINA

The Provision of ETO Sterilization services for Medical Devices

Allmed Medical Products Co., Ltd.-Jianli

No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County, 433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA

The Provision of ETO and Moist Heat Sterilization services for **Medical Devices**

Supplement to Quality System Certificate

No. SUP 002037 0011 Rev. 02

This supplement is only valid in conjunction with the main certificate:

Q8 002037 0002 Rev. 03

Certificate Holder:

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

Facility(ies): Allmed Medical Products Co., Ltd.

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

Allmed Medical Products Co., Ltd.-Jianli

No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County, 433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

> EN ISO 11135:2014 "Sterilization of health-care products -Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)"

Audit Report: SH2225601 Dated: 2022-07-07

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

Valid from: 2022-12-28

Christoph Dicks

Head of Certification/Notified Body



Supplement to Quality System Certificate

No. SUP 002037 0012 Rev. 02

This supplement is only valid in conjunction with the Q8 002037 0002 Rev. 03

Certificate Holder:

main certificate:

Allmed Medical Products Co., Ltd

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

Facility(ies):

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.-Jianli

No.168-1(Te), Yusha Road, Rongcheng Town, Jianli County, 433300 Jingzhou, Hubei, PEOPLE'S REPUBLIC OF CHINA

The quality system certified as stated in the main certificate additionally fulfills the applicable requirements of

> EN ISO 17665-1:2006 "Sterilization of health care products -Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for

medical devices (ISO 17665-1:2006)"

Audit Report:

SH2225601

Dated:

2022-07-07

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

Valid from:

2022-12-28

Christoph Dicks

Head of Certification/Notified Body

No.18 Qi Xing Road, Majiadian Town, 443200 Zhijiang City, Hubei Province, P.R.C

Tel: 86 717 4211111

Fax: 86 717 4225499



Declaration of Conformity

Manufacturer: Allmed Medical Products Co..Ltd

Address: No.18 Qi Xing Road, Majiadian Town, 443200Zhijiang City, Hubei province,

PEOPLE' S REPUBLIC OF CHINA

SRN: CN-MF-000007970

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

The complete Product Listing shown on Annex Nr1.

Conformity Assessment Route: Annex II and III of Regulation (EU) 2017/745

We herewith declare in our own responsibility that the above mentioned products meet the Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Regulation and standard

Medical Device Regulation: The object of the declaration described above is in conformity with

Regulation (EU) 2017/745

Common specifications: Not Applicable

Standard Applied: all applicable harmonised standard (published in the official journal of the

European Communities)

ISO 13485:2016 Certificate: Q5 002037 0008 Rev. 02

Expire date of the Certificate: 2022-08-31

Place, Date of Issue: Hubei province, P.R.C,2020-09-01

Signature: Nov. 3°. 2022

General Manager of Quality

Position:

ANNEX Nr. 1 To DoC number: DoC M0301 The medical devices which fall under the DoC are:

Product category: Gauze Bandages

REF Code	SIZE	Product Description	EMDN Code	
AM-GB10500	10cm x 5m	Non-Sterile Gauze Bandage, 32g/m2, 10cm x 5m, individually packed	M030101	
AM-GB10500-12	10cm x 5m	Non-Sterile Gauze Bandage, 32g/m2, 10cm x 5m, pack of 12 pcs	M030101	
AM-GB14700	14cm x 7m	Non-sterile Gauze Bandage, 32g/m2, 14cm x 7m, individually packed	M030101	
AM-GB14700-12	14cm x 7m	Non-Sterile Gauze Bandage, 32g/m2, 14cm x 7m, pack of 12 pcs	M030101	
AM-GR90-90-24A	Width 90cm, Length: 90m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 90m	M0201	
AM-GR90-90-24A- 1	Width 90cm, Length: 1m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 1m	M0201	
AM-GR90-90-24A- 2	Width 90cm, Length: 2m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 2m	M0201	
AM-GR90-90-24A- 5	Width 90cm, Length: 5m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 5m	M0201	
AM-GR90-90-24A- 10	Width 90cm, Length: 10m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 10m	M0201	
AM-GR90-90-24A- 20	Width 90cm, Length: 20m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 20m	M0201	
AM-GR90-90-24A- 50	Width 90cm, Length: 50m	Non-Sterile Gauze Roll, 32g/m2, width 90cm length: 50m	M0201	

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ANNEX Nr. 1 To DoC number: DoC M0301 The medical devices which fall under the DoC are:

Product category: Gauze Bandages

AM-GR90-90-24A-	Width 90cm,	Non-Sterile Gauze Roll,	
100	Length: 100m	32g/m2, width 90cm,	M0201
		length: 100m	

REF Code	SIZE	Product Description	EMDN Code M030101	
AM-GB10500-27	10cm x 5m	Non-Sterile Gauze Bandage, 27g/m2, 10cm x 5m, individually packed		
B 1		Non-Sterile Gauze Bandage, 27g/m2, 10cm x 5m, pack of 12 pcs	M030101	
AM-GB14700-27	14cm x 7m	Non-sterile Gauze Bandage, 27g/m2, 14cm x 7m, individually packed	M030101	
AM-GB14700-12-27	14cm x 7m	Non-Sterile Gauze Bandage, 27g/m2, 14cm x 7m, pack of 12 pcs	M030101	
AM-GR90-90-24A-27	Width 90cm, Length: 90m	Non-Sterile Gauze Roll, 27g/m2, width 90cm, length: 90m	M0201	
AM-GR90-90-24A-1-27	Width 90cm, Length: 1m	Non-Sterile Gauze Roll, 27g/m2, width 90cm, length: 1m	M0201	
AM-GR90-90-24A-2-27	Width 90cm, Length: 2m	Non-Sterile Gauze Roll, 27g/m2, width 90cm, length: 2m	M0201	
AM-GR90-90-24A-5-27	Width 90cm, Length: 5m	Non-Sterile Gauze Roll, 27g/m2, width 90cm, length: 5m	M0201	
AM-GR90-90-24A-10-27	Width 90cm, Length: 10m	Non-Sterile Gauze Roll, 32g/m2, width 90cm, length: 10m	M0201	
AM-GR90-90-24A-20-27	Width 90cm, Length: 20m	Non-Sterile Gauze Roll, 27g/m2, width 90cm, length: 20m	M0201	



ANNEX Nr. 1 To DoC number: DoC M0301 The medical devices which fall under the

DoC are:

Product category: Gauze Bandages

AM-GR90-90-24A-50-27	Width 90cm,	Non-Sterile Gauze	
	Length: 50m	Roll, 27g/m2, width	M0201
		90cm, length: 50m	老压处
AM-GR90-90-24A-100-27	Width 90cm,	Non-Sterile Gauze	Z T L L
	Length: 100m	Roll, 27g/m2, width	M0201
		90cm, length: 100m	展
			HD
			JA WELL

Vine (ian 1991. 30. 2022 No.18 Qi Xing Road, Majiadian Town, 443200 Zhijiang City, Hubei Province, P.R.C



Tel: 86 717 4211111

Fax: 86 717 4225499

Declaration of Conformity

Manufacturer: Allmed Medical Products Co.,Ltd

Address: No.18 Qi Xing Road, Majiadian Town, 443200Zhijiang City, Hubei province, PEOPLE' S REPUBLIC OF CHINA

European Representative: Shanghai International Holding Corp. GmbH(Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

The complete Product Listing shown on Annex Nr1.

Classification(MDD,Annex XI): I sterile

Classification Rule:4

Conformity Assessment Route: MDD93/42/ EEC Annex V.

We herewith declare in our own responsibility that the above mentioned products meet the transportation into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. We are exclusively responsible for the declaration of conformity.

Directives

Medical Device Regulation: The object of the declaration described above is in conformity with Council Directive MDD 93/42/EEC.

Standard Applied: all applicable harmonised standard (published in the official journal of the European Communities)

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 MÜnchen, Germany

Identification number: 0123

Certificate: Q5 002037 0008 Rev. 02 Expire date of the Certificate: 2024-05-26

Start of CE Marking:not start

Signature

Place, Date of Issue: Hubei province, P.R.C,2020-09-01

General Manager of Quality

Position:

ANNEX Nr. 1 To DoC number: DoC 11859 The medical devices which fall under the DoC are:

Product category: Gauze Bandages

REF Code	SIZE	SIZE Product Description	
AM-GB10500-S	10cm x 5m	Sterile Gauze Bandage, 32g/m2, 10cm x 5m	M030101
AM-GB14700-S	14cm x 7m	Sterile Gauze Bandage, 32g/m2, 14cm x 7m	M030101

REF Code	SIZE	Product Description	EMDN Code	
AM-GB10500-S-27	10cm x 5m	Sterile Gauze Bandage, 27g/m2, 10cm x 5m		
AM-GB14700-S-27	14cm x 7m	Sterile Gauze Bandage, 27g/m2, 14cm x 7m	M030101	

Nov. 30. a. 22



ALLMED MEDICAL PRODUCTS CO.,LTD

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

Quality Report

(Absorbent Cotton Gauze)

Report No: 2306001 Report Date: 2023.06.02 制造商 ALLMED MEDICAL PRODUCTS 产品号 AM CRASSOS CAM CRASSOS CAM

制 造 商 Manufacturer	ALLMED MEDICAL PRODUCTS CO.,LTD	Re	产品号 eference No. AM-GB10500-S/AM-GB		14700-S
规 格 Specification	40s×40s/30×30 Gauze		订单号 PO# 2023002		
检验数量 Inspection Quantity	5m		检测时间 espection Date 2023.04.11		
特征 Characteristic	EN14079 要求 结果 REQUIREMENT OF EN14079 RESULT		RESULT	判定 Complies (Yes or No	
纤维鉴别 Fibre Identification	符合 IDENT 试验 A、B、C 项 Shall conform to the IDENT tests A, B and C		A、纤维呈扁平带状。端部增粗且有内腔。 Fibre consists of single cell, in the form of flattened tube with thick and rounded walls and often twisted. B、纤维显紫色。 Fibre becomes violet with iodinated zinc chloride solution. C、纤维未溶解。 Fibre does not dissolve		Yes
酸碱度 Acidity and alkalinity	两种溶液均不得显粉红色 No pink colour develops in either portion		未显粉红色 No pink colour develops in either portion		Yes
外来纤维 Foreign fibres	只允许出现少量孤立的外来纤维 Only occasionally a few isolated foreign fibres allowed		未见外来纤维 No isolated foreign fibres		Yes
荧光 Fluorescence	不允许显示深蓝色纤维 No intense blue fluorescence shall be displayed		未见深蓝色纤维 No intense blue fluorescence displayed		Yes
经密 Warp	120±6th/100mm		116 th/100mm		Yes
纬密 Weft	120±6th/100mm		115 th/100mm		Yes
平方米克重 Mass per square metre	≥ 32.0 g/m²		32.25 g/m ²		Yes
最小断裂强度 Minimum breaking load	MD: ≥60N CD: ≥50N		MD:109.0N; CD:89.5N		Yes
吸水时间 Sinking time	≤10 s		1.21s		Yes
醚中可溶物 Ether-soluble substances	≤0.5%		0.29%		Yes
表面活性物 Surface active substances	≤2mm		1.0mm		Yes
水中可溶物 Water-soluble substances	≤0.5%		0.20%		Yes
淀粉和糊精 Starch and dextrin	不得显示蓝、紫、微红或褐色 Shall not show any blue, violet, reddish or brownish colour		develops		Yes
可浸提的着色物质 Extractable colouring matter	不超过参考溶液 Y5 或 GY6 Shall not be more intensely color than reference solution Y5, GY		颜色未超过溶液 Y5 Colour is less intense than reference solution Y5		Yes
干燥失重 Loss on drying	≤ 8.0%		4.02%		Yes
硫酸盐灰份 Sulphated ash	≤ 0.40%			0.13%	Yes
结论 Conclusion	Complies with EN14079				

审核 (Reviewed): _

You Dequan

准备 (Prepared By): _

1 OF 1

Zheng Qiong