No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City,
Hubei Province, P.R.C
Tel: 86 717 4211111 Fax: 86 717 4225499

ALLMED

WI-CE-A

Declaration of Conformity

Manufacturer: Allmed Medical Product s Co, Ltd

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

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

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Drain Sponges ,Post-Op Sponges , Cotton-Filled Exodontia Sponges, Non Stick Pads, Non Woven Swabs
UMDNS Code: 13695
Model Number: Please refer to List of CE-labeled Products.
Classification (MDD, Annex IX):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 transposition 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 Directive: The object of the declaration described above is in conformity with the 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
(EC) Certificate(s): G2S 002037 0010 Rev.02
Expire date of the Certificate: 2024-05-26
Start of CE Marking: 2018-03-28
Place, Date of Issue: Hubei, 2020-09-01

Signature: Vinie Tian

Name: Sep.01.2020

General Manager of Quality

Position:

No.18 Qixing Road, Majiadian Town, 443200 Zhijiang City,
Hubei Province, P.R.C
Tel: 86 717 4211111 Fax: 86 717 4225499

ALLMED

STATEMENT

Herewith Allmed Medical Products Co.Ltd.,declares ,

The DOC for sterile non woven swabs we provide to Systagenix Wound Management Limited can cover the following product code,and the model number can be included into List of CE-labeled Products.

FPS Specification Doc#:FPS-TOPPER -STERILE(Rev2)

Brand Name	Product Name	Sterilization	Product Code	Specification
Topper	non woven swabs	EO sterile	TS8102	10x10cm-4P
Topper	non woven swabs	EO sterile	TS8105	10x10cm-4P
Topper	non woven swabs	EO sterile	TS1102	10x10cm -6P
Topper	non woven swabs	EO sterile	TS1105	10x10cm-6P
Topper	non woven swabs	EO sterile	M12510	10x10cm-4P
Topper	non woven swabs	EO sterile	P55552	7.5x7.5cm-4P
Topper	non woven swabs	EO sterile	TS8072	7.5x7.5cm-4P
Topper	non woven swabs	EO sterile	TS8075	7.5x7.5cm-4P
Topper	non woven swabs	EO sterile	TS1072	7.5x7.5cm-6P
Topper	non woven swabs	EO sterile	TS1075	7.5x7.5cm-6P
Topper	non woven swabs	EO sterile	M12507	7.5x7.5cm-4P
Topper	non woven swabs	EO sterile	TS8052	5x5cm-4P
Topper	non woven swabs	EO sterile	TS8055	5x5cm-4P
Topper	non woven swabs	EO sterile	TS1052	5x5cm-6P
Topper	non woven swabs	EO sterile	MCKK100	5x5cm-6P
Topper	non woven swabs	EO sterile	TS8202	10x20cm-4P
Topper	non woven swabs	EO sterile	TS1202	10x20cm-6P
Topper	non woven swabs	EO sterile	TS1205	10x20cm-6P

Signature:

Print Name: DequanYou

Position: RA Manager

Company: Allmed Medical Products Co.,Ltd

Date: 2022-09-08

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 002037 0015 Rev. 01

Manufacturer:

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

SRN Manufacturer - CN-MF-000007970

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex XI Part A of this regulation with a positive result.
As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality assurance system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G21 002037 0015 Rev. 01

Report No.: SH2425601

Preceding Certificate No.: G21 002037 0015 Rev. 00

Valid from: 2025-03-19
Valid until: 2028-07-09

Date of Initial Issuance: 2023-07-10

Issue date: 2025-03-19

Christoph Dicks
Head of Certification/Notified Body

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BS-MDR-099

TÜV SÜD Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 002037 0015 Rev. 01

Classification:	Class I
Device Group:	V01 - CUTTING DEVICES, SINGLE-USE
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	M01 - COTTON AND SYNTHETIC WADDING
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	M02 - GAUZES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	M03 - BANDAGES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	M04 - SPECIAL DRESSINGS
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization MDS 1005.3 - Sterilization by moist heat

Classification:	Class I
Device Group:	T01 - GLOVES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T02 - PROTECTIVE CLOTHING AND DRAPES (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	T04 - INCONTINENCE DEVICES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

Classification:	Class I
Device Group:	V90 - VARIOUS DEVICES NOT INCLUDED IN OTHER CLASSES
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

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Product Service

EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G21 002037 0015 Rev. 01

Classification:	Class I
Device Group:	V04 - CLINICAL USE CONTAINERS (NON-IVD)
Device Properties:	MDS 1005.1 - Ethylene Oxide sterilization

The validity of this certificate depends on conditions and/or is limited to the following: /

Revision History:

Rev.	Dated	Report	Description
00	2023-07-10	SH2125602	Initial issuance
01	2025-03-19	SH2425601	Supplemented: Device(s)/group of device(s) added

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