

WI-CE-A

Declaration of Conformity

Manufacture: Allmed Medical Products Co, Ltd

Address: No.18 Qi Xing 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: Non Woven Swabs

UMDNS Code: 13695

GMDN Code: 48131

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.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: 2018-03-28

Place, Date of Issue: Hubei, 2019-08-09

Signature: You Dequan 2019.10.09 RA Manager
Name: _____ Position: _____

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 (Rev1).

Brand Name	Product Name	Sterilization	Product Code	Specification
Topper	non woven swabs	EO sterile	TS8102	10 x 10 cm-4P
Topper	non woven swabs	EO sterile	TS8105	10 x 10 cm-4P
Topper	non woven swabs	EO sterile	TS1102	10 x 10 cm-6P
Topper	non woven swabs	EO sterile	TS1105	10 x 10 cm-6P
Topper	non woven swabs	EO sterile	M12510	10 x 10 cm-4P
Topper	non woven swabs	EO sterile	P55552	7.5 x 7.5 cm-4P
Topper	non woven swabs	EO sterile	TS8072	7.5 x 7.5 cm-4P
Topper	non woven swabs	EO sterile	TS8075	7.5 x 7.5 cm-4P
Topper	non woven swabs	EO sterile	TS1072	7.5 x 7.5 cm-6P
Topper	non woven swabs	EO sterile	TS1075	7.5 x 7.5 cm-6P
Topper	non woven swabs	EO sterile	M12507	7.5 x 7.5 cm-4P
Topper	non woven swabs	EO sterile	TS8052	5 x 5 cm-4P
Topper	non woven swabs	EO sterile	TS8055	5 x 5 cm-4P
Topper	non woven swabs	EO sterile	TS1052	5 x 5 cm-6P
Topper	non woven swabs	EO sterile	MCKK100	5 x 5 cm-6P
Topper	non woven swabs	EO sterile	TS8202	10 x 20 cm-4P
Topper	non woven swabs	EO sterile	TS1202	10 x 20 cm-6P
Topper	non woven swabs	EO sterile	TS1205	10 x 20 cm-6P

Signed: *You Dequan*

Print Name: Dequan You

Position: QA Manager

Company: Allmed Medical Products Co.,Ltd

Dated: 2018.05.17