

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:

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 Cutting Gauze (with or without X-Ray Thread)

UMDNS Code: 13705

Model Number: Please refer to List of CE-labeled Products.

Classification (MDD, Annex IX): II_a

Classification Rule:7

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): G2 002037 0009 Rev.01

Expire date of the Certificate: 2024-05-26

Start of CE Marking: Not start

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

Signature: Vincent Tian

Name:

General Manager of Quality

Position: