

Declaration of Conformity

Manufacturer:

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

Address: Industrial Park, Jiangdu Bridge, Yangzhou, 225211 Jiangsu P.R. China

Tel: 0086-514-86976213 Fax: 0086-21-51861120

Authorized Representative:

Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Surgical Drapes

Classification: Class Is, Rule 1, Annex IX, MDD 93/42/EEC

UMDNS No.: 15705

Specification: Drapes

Conformity Assessment Route: Annex V

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards, the standards of EN ISO 13485:2016 and BS EN 13795-1:2019. All supporting documentations are retained under the promises of the manufacturer: Jiangsu Medplus Non-woven Manufacturer Co., Ltd. Is exclusively responsible for Declaration of Conformity.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 5 Sept 2007 concerning medical devices.

Notified Body: TÜV Rheinland LGA Products GmbH

Address of Notified Body: Tillystraße 2, 90431, Nürnberg, Germany

Identification number: CE0197

(EC) Certificate(s): DD 2063039-1

Expire date of the Certificate: 2024-05-26

Start of CE marking: 2020-09-11

Place, Date of Issue:

Yangzhou, Jiangsu

09/13/2020

General Manager

(Name and signature or equivalent
Marking of authorized person)

