

EU Declaration of Conformity

Manufacturer:

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

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

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SRN:CN-MF-000022548

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Authorized Representative:

Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

SRN:CN-MF-000022548

DE-AR-000000001

Product Name: Sterile Surgical Gowns

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

UMDNS No.: 11901

Specification: lab coats (XS/S/M/L/XL/XXL/XXXL), isolation gowns (XS/S/M/L/XL/XXL/XXXL), surgical gowns (XS/S/M/L/XL/XXL/XXXL), coveralls (XS/S/M/L/XL/XXL/XXXL), scrub suit (XS/S/M/L/XL/XXL/XXXL).

Conformity Assessment Route: Annex VII

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.

Start of CE Marking: 02/07/2020

Place, Date of Issue:

Yangzhou, Jiangsu

02/15/2020

Manager

(Name and signature or equivalent
Marking of authorized person)

