



JIANGSU MEDPLUS NON-WOVEN MANUFACTURER CO.,LTD.

No.217 East Wencheng Road, Economic Development Zone, Siyang, Jiangsu 223700, China

TEL:+86-21-50132506; Email: info@cnmedplus.com

EU Declaration of Conformity

Manufacturer:

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

Address 1: Industrial Park, Jiangdu Bridge, Yangzhou, 225211 Jiangsu P.R. China

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

Address 2: No.217 East Wencheng Road, Economic Development Zone, Siyang, 223700

Jiangsu P.R. China

Tel: +86-527 8030 0123 Fax: +86 21 5186 1120

Authorized Representative:

Shanghai International Holding Corp. GmbH(Europe)

Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Disposable 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).

Product:

REF	Name
5541	Suavel OP PRO Standard
5542	Suavel OP PRO Standard
5543	Suavel OP PRO Standard
5544	Suavel OP PRO Standard
5551	Suavel OP PRO Expert
5552	Suavel OP PRO Expert
5553	Suavel OP PRO Expert
5554	Suavel OP PRO Expert

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



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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

10/13/2022

Manager: Alen

(Name and signature or equivalent
Marking of authorized person)