

EU Declaration of Conformity

Manufacturer:

Jiangsu Medplus Non-woven Manufacturer Co., Ltd.

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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

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 V

We hereby declare that the above product complies with the requirements and applicable standards of the transitional provisions of Article 120 of the Medical Devices Regulation (EU) 2017/745, and that we have applied to the Notified Body for MDR certification in accordance with the requirements of Section 4.3 of Appendix VII of the MDR.

TÜV Rheinland LGA Products GmbH has also certified that the product can continue to be placed on the market until December 31, 2028 by issuing a product extension declaration.

Notified Body: TÜV Rheinland LGA Products GmbH

Identification number: CE₀₁₉₇

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

Start of CE marking: 2020-09-11

Place, Date of Issue:

siyang, Jiangsu

06/19/2024

Manager

Alan

(Name and signature or equivalent
Marking of authorized person)