EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number: CE 706247

In respect of:

Model OPS™ Essential protective surgical gowns
To BS EN 14605:2005+A1:2009 and EN 14126:2003

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Denelise L'Ecluse, Managing Director Assurance - Continental Europe

First Issued: 2019-03-08
Latest Issue: 2024-01-09

Effective Date: 2024-01-09
Expiry Date: 2029-03-08

PRODUCTS
RvA C 646

This certificate has been issued by and remains the property of BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands and should be returned immediately upon request.
To check its validity telephone +31 20 3460780. An electronic certificate can be authenticated online.

BSI Group The Netherlands B.V., registered in the Netherlands under number 33264284, at John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
A member of BSI Group of Companies.

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No. CE 706247

Product Specification:

Range: OPS™ Essential

Models in Range:
S3500P
S3510P
NS-S3510P
S3540P
NS-S3540P
S3513P
NS-S3513P
S3581P
NS-S3581P

Product Description: The OPS™ Essential surgical gowns, are composed of non-woven fabrics, used as barriers between the patient and the physician, and between the patient and surgical environment. The surgical gown contains reinforced areas on the front of the gowns and on the sleeves. The surgical gowns are intended to protect the wearer against chemicals and infective agents only on the reinforced area.

Sizes: S/M, L, XL, XLL, 2XLL

Classification:
Category III PPE (Complex)
Type PB [4]-B

Technical Specification: EN 14605:2005+A1:2009 Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4]).
EN 14126:2003 Protective clothing — Performance requirements and tests methods for protective clothing against infective agents.

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Certificate Administration Details:

Technical File Reference: EU1-00004-F-00007_FINT.475_STED TF n°26.

Certificate Administration Record:

Issue Date	Comments	BSI Project Ref.
March 2019	First issue under PPE Regulation (EU) 2016/425, product initially approved to Article 10 of the PPE Directive 89/686/EEC under BSI issued certificate CE 654108	0086:19:9715857
September 2023	Reissue – admin updates and change to Module D surveillance.	2797:23:3868671
January 2024	Reissue – certificate 5 years expiry renewal.	2797:24:30051507

Certificate validity:

The Certificate holder is responsible for ensuring that the Notified Body is advised of changes to any aspect of the overall process utilised in the manufacture of the product, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

Monitoring of manufactured PPE

The validity of the Certificate for the products is also dependent on the maintenance of the EU Conformity to Type Based on Quality Assurance of the Production Process, Annex VIII (Module D), as referenced on BSI issued Certificate CE 787348.

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