EU Type Examination Certificate

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number: CE 706248

In respect of:

Model Prevention Plus isolation gowns, surgical gowns, sleeves and boot covers
To 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

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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 706248

Product Specification

Range: Prevention™ Plus

Models in Range:
NONE27457 Isolation gown, L, 114 cm
NONE27457XL Isolation gown, XL, 127 cm
DYNJPE2301P Surgical Gown, L, 114 cm
DYNJPE2302P Surgical Gown, XLL, 140 cm
E21394P Surgical Gown, XLL, 140 cm, non-sterile
598CE Sleeves with cuffs
NONE27348PXL Boot Covers

Product Description: The Prevention™ Plus gowns consist of a 3 layer breathable and impervious Polypropylene non-woven and Polyethylene film material. The surgical gowns and isolation gowns have ultrasonic welded seams. The material at the back overlaps when the gown is worn and is fastened by a belt and the adjustable hook and loop closure at the neck. The isolation gowns have a reduced overlap at the back. Prevention™ Plus protective clothing is intended to protect the wearer against chemotherapy drugs and infective agents. The protection is effective for the whole garment. Prevention™ Plus isolation gowns are not intended to be used during surgery as physical barrier between the surgeon and the patient for prevention of SSI. The surgical gowns are intended to protect the wearer against chemicals and infective agents. Separate sleeves and boot covers are also available to be worn with the gowns. They are worn by healthcare professionals for their protection during other medical care outside the OR. In particular, administration of chemotherapeutic agents.

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

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

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Product Specification (continued)

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

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 688014	0086:19:9715858
November 2021	Extension of scope to include protection from infective agents	2797:21:3446907
September 2023	Reissue – admin updates and transfer to Module D surveillance.	2797:23:3868672
January 2024	Reissue – certificate 5 years expiry renewal.	2797:24:30051508

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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