Conformity to Type based on Quality Assurance of the Production Process

This is to certify that:

Medline International France SAS
5 Rue Charles Lindbergh
Châteaubriant
44110
France

Holds Certificate Number: CE 787348

In respect of:

For the manufacture of Protective Surgical and Isolation Gowns, Sleeves and Boot Covers

on the basis that BSI carried out the quality assurance assessment under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VIII (Module D)

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: 2023-09-01
Latest Issue: 2023-09-01

Effective Date: 2023-09-01
Expiry Date: 2028-08-31

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.

Conformity to Type based on Quality Assurance of the Production Process

No. CE 787348

PPE Module B Certificate holding location:

Medline International France SAS
5 Rue Charles Lindbergh, Châteaubriant, 44110
France

Manufacturing Sites:

Product manufactured at the locations and processes detailed in accordance with PPE Regulation (EU) 2016/425; referenced in Technical File EU1-00004-F-00007_FINT.475_STED TF n°26 under BSI Module B certificates: CE 706247 and CE 706248.

Harmonised Standards:	Product Type
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 Record

Issue Date	Comments	BSI Project Ref.
September 2023	First issue under PPE Regulation (EU) 2016/425.	2797:23:3874897

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 products, failure to do so could invalidate the Certificate in respect of product manufactured following the introduction of such changes.

The validity of the Certificate is also dependent on the maintenance of an ISO 9001 quality system certified by a recognized certification organisation.

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