Language of this declaration: **en English** (translations available in the following pages)

Declaration of conformity n° DC 208
Revision n° 03
Technical file # 02A - 02B

Legal manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant - France **Single Registration Number** FR-MF-000000676
EU representative	Not applicable **Single Registration Number** Not applicable
UK representative	Medline Industries Ltd, WA4 6HL, UK
Product type	Protective clothing – Impervious cover gown
Intended use	Intended to be worn by healthcare professionals around an operating room, intensive care unit or immunodepressed patient to protect the patient from potential contamination.
Product codes	See attached list
GMDN codes	See attached list
EMDN codes	See attached list

European Union Regulations:

We herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the following EU Regulations and/or Council Directive(s) as transposed into national laws.

Applicable regulation:	**Medical Device: Regulation (EU) 2017/745 of 5 April 2017**
Medical Device classification	Class I; Rule n°1
Applicable standards and/or Common Specifications are listed in technical file n°:	02A
Conformity assessment procedure	Annex II and III
Certificate n°	Not applicable, self Declaration
Notified Body	Not applicable, self Declaration

Applicable regulation:	**PPE Regulation (EU) 2016/425 of 9 March 2016**
Risk categories of PPE	Category I; Risk: Protection against minimal risk: prolonged contact with water that could occur in the medical environment
Applicable standards or technical specification:	ISO 811:2018, EN 16523-1:2018, EN 14325:2018
Conformity assessment procedure(s)	
☒ Module A set out in Annex IV of Regulation	
☐ Module B set out in Annex V of Regulation	Not applicable
EU-type examination Certificate n°	Not applicable
Notified Body (name/number)	

The PPE is subject to the following conformity assessment procedure under surveillance of Not applicable

☐ Module D set out in Annex VIII: Conformity to type based on quality assurance of the production process

UK Regulations

We herewith declare under our sole responsibility that the above-mentioned products comply with:

UK Medical device Regulation 2002 as amended

Medical Device Classification Class I; Rule n°1

UKCA Conformity assessment procedure: Part II, Annex VII as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

UKCA certificate n°: Not applicable, self Declaration

UKCA Approved Body: Not applicable, self Declaration

UK designated standards or technical specification: Same as EU standards

Australian Regulations:

This is a declaration of conformity made under clause 6.6 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002. Each kind of medical device to which the declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

Authorised Signatory:

Stanley Dorvilly

Digitally signed by Stanley Dorvilly
DN: cn=Stanley Dorvilly, o=Medline International France, ou=Medline International France, email=Stanley.Dorvilly@medline.com, c=FR
Date: 2024.11.12 08:39:57 +01'00'

Stanley Dorvilly - Regulatory Affairs Director	44110 Châteaubriant - France	12 Nov 2024
Name - Title	*Place*	*Date*

Retention period: 10 years after the end of life

DC Number: DC208 **Rev:** 03

(en) Product Code(s)	(en) GMDN code	(en) EMDN code	(en) Basic UDI-DI
(fr) Codes produits/ (de) Produkt-Code (s)/ (it) Codici dei prodotti/(es) Código(s) de producto/ (pt) Código(s) de produto/ (nl) Productcode(s)/ (sv) Artiklenummer/ (da)Produktkode/ (fi)Tuotekoodi(t)/ (pl) Kod(y) produktu/ (ro) Codul(codurile) produsului/(cs) Kód(y) výrobku/ (el) Κωδικός(οι) προϊόντος/ (hu) Termékkód(ok)/ (sk) Kód(-y) produktu/ (sl) Kode izdelka	(fr) code GMDN/ (de) GMDN code/ (it) Codici GMDN / (es) Código GMDN / (pt)Código GMDN / (nl) GMDN-code/ (sv) GMDN kod/ (da) GMDN kode/ (fi) GMDN-koodi/ (pl) Kod GMDN/ (ro) Cod GMDN/ (cs) Kód GMDN/ (el) Κωδικός GMDN/ (hu) GMDN kód/ (sk) Kód GMDN / (sl) Kode GMDN	(fr) code EMDN/ (de) EMDN code/ (it) Codici GMDN/ (es) Código EMDN/ (pt) Código EMDN/ (nl) EMDN-code/ (sv) EMDN kod/ (da)EMDN kode/ (fi) EMDN-koodi/ (pl) Kod EMDN/ (ro) Cod EMDN/ (cs) Kód EMDN/ (el) Κωδικός EMDN/ (hu) EMDN kód/ (sk) Kód EMDN/ (sl) Kode EMDN	(fr) IUD-ID de base/ (de) Basis-UDI-DI/ (it) UDI-DI di base/ (es) UDI-DI básico/ (pt) UDI-DI básico/ (nl) Basic UDI-DI/ (sv) grundläggande UDI-DI/ (da) Den grundlæggende UDI-DI/ (fi) yksilöllisen UDI-DI-tunnisteen/ (pl) Kod Basic UDI–DI/ (ro) UDI-DI de bază/ (cs) základního UDI-DI/ (el) βασικό UDI-DI/ (hu) alapvető UDI-DI/ (sk) Základný UDI-DI/(sl) Osnovni UDI-DI
NONELV350	35492	T0205	0888277DC208NSK4

GMDN Code only for products classified as Medical devices.	
35492	Isolation gown, single-use