Declaration of Conformity

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

EU Declaration of conformity n° DC207
Revision n° 00
Technical file n° 02 B

Legal manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant - France
EU representative	N/A
Product type	Protective clothing : Impervious Cover Gown
Product Code(s)	See attached list
GMDN Code(s)	N/A

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 N/A; Rule n°N/A
Conformity assessment procedure	Annex N/A
Certificate n°	N/A
Notified Body (name/number)	N/A
Applicable standards are listed in technical file n°	N/A

Applicable regulation:	**Personal Protective Equipment: 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 - cleaning materials of weak action
Applicable standards are listed in technical file n°	02 B

Conformity assessment procedure(s)

☒ Module A set out in Annex IV of Regulation

☐ Module B set out in Annex V of Regulation
EU-type examination Certificate n° N/A
Notified Body (name/number) N/A

☐ Module C set out in Annex VI of Regulation

Where applicable, the PPE is subject to the following conformity assessment procedure under surveillance of the notified body (name, number): N/A

☒ Module C2 set out in Annex VII of Regulation :
Conformity to type based on internal production control plus supervised product checks at random intervals

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

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.

All supporting documentation is retained at the premises of the manufacturer.

Authorised Signatory:

Kenneth Smith	44110 Châteaubriant - France	24/01/2019
International Quality Operations Manager	*Place*	*Date*

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