Declaration of Conformity

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

EU Declaration of conformity n°	DC_Prevention Plus Surgical Gown-Non sterile
Revision n°	01
Technical file n°	01 - 26

Legal manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant - France	
	Single Registration Number	Not available
EU representative	Not applicable	
	Single Registration Number	Not applicable
Product type	Protective clothing - Prevention Plus	
Product Code(s)	NS-E21394P	
GMDN Code(s)	35091	

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 directive :	**Medical Device:** **Directive 93/42/EEC of 14 June 1993 as amended.**
Medical Device classification	Class I; Rule n°1
Applicable standards and/or Common Specifications are listed in technical file n°:	01
Conformity assessment procedure	Annex VII
Certificate n°	Not applicable, self Declaration
Notified Body (name/number)	Not applicable, self Declaration
Applicable regulation:	**Personal Protective Equipment:** **Regulation (EU) 2016/425 of 9 March 2016**
Risk categories of PPE	Category III; Risk: Substances and mixtures which are hazardous to health
Applicable standards are listed in technical file n°	26

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° CE 706248
  - Notified Body (name/number) BSI (2797)
- ☐ 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): BSI (2797)

- ☒ 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 technical documentation applies complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Authorised Signatory:

Kenneth Smith	44110 Châteaubriant - France	07/11/2019
Senior QA/RA Manager	*Place*	*Date*