Declaration of Conformity

Declaration of conformity n° **DC202**
Revision n° **18**
Technical file # **02 A**

Manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant France	**Single Registration Number of the Manufacturer**	Not Available
Product range	Protective Device Apparels : Headwears, Footwears, clean Air Suits, scrub suits, examination gowns and cover gowns		
Product codes	See attached list		
Classification	Class I Non-sterile, Rule 1		
GMDN 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**
Conformity assessment procedure per MDR 2017/745	Annex II & III
Notified Body	Not applicable
Certificate n°	Not applicable
First Issued (Place/Date)	Not applicable
Applicable standards and/or Common Specifications	Listed in technical file 02 A

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.

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

Authorised Signatory:

Kenneth Smith *Senior QA/RA Manager*	44110 Châteaubriant - France *Place*	03/05/2019 *Date*