Declaration of Conformity

Declaration of conformity n°	**DC Curad Latex**
Revision n°	**00**
Technical file #	**09 (MDD) and 24 (PPE)**

Manufacturer	**Medline International France SAS** 5 rue Charles Lindbergh 44110 Châteaubriant France
Product	Examination Gloves – Curad Latex
Product Codes	CURE8103, CURE8104, CURE8105, CURE8106, CURE8107
Medical Device class/rule	Medical Device class I NS – rule 5
PPE Category	Personal Protective Equipment Category III
GMDN Codes	47172 Hevea-latex examination/treatment glove, non-powdered, non-sterile

European Union Regulations:

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

Applicable directive:	Medical Devices Directive: Council Directive 93/42/EEC of 14 June, 1993 as amended.
Annex 93/42/EEC	VII
Notified Body	N/A
Certificate n°	N/A
First Issued (Place/Date)	N/A
Applicable standards	See Technical File 09

Applicable directive: Personal Protective Equipment: Council Directive 89/686/EEC of 21 December 1989.

EC-type examination per Article 10

Certificate n°	CE 653419
Notified Body (name/number/address)	BSI (0086), MK5 8PP, UK
First Issued (Place/Date)	The United Kingdom, 25th May 2016
Applicable standards	See Technical File 24

Conformity assessment procedure per Article 11

Article 11 A or B	Article 11A
Certificate n°	CE 653430
Notified Body (name/number/address)	BSI (0086), MK5 8PP, UK
First Issued (Place/Date)	The United Kingdom, 25th May 2016

Australian Regulations:

This declaration is made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian **Therapeutic Goods (Medical Devices) Regulations 2002** relating to the stated devices.

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

Authorised Signatory:

Kenneth Smith	44110 Châteaubriant - France	31/05/2016
International Quality Operations Manager	*Place*	*Date*