Declaration of Conformity for Medline US products

Declaration of conformity n° DC_Sensicare PI
Revision n° 01
Technical file # CE2009005 (MDD) and CEP2009005 (PPE)

Legal Manufacturer	Medline Industries, Inc. Three Lake Drive, Northfield, illinois 60093 USA
EC Representative	Medline International France SAS 5 rue Charles Lindbergh, 44110 Châteaubriant - France
Product range	Surgical Gloves – Sensicare PI
Product codes	See attached list
Classification	Medical Device class IIa Sterile - rule 6 Personal Protective Equipment Category III
GMDN Codes	56293 Polyisoprene surgical glove, non-powdered

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	Annex II
Notified Body	BSI The united Kingdom – CE 0086
Certificate n°	CE 557201
First Issued (Place/Date)	The United Kingdom, 20th january, 2010
Applicable standards	See Technical File CE2009005

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

EC-type examination per Article 10

Certificate n°	CE 664227
Notified Body (name/number/address)	BSI The united Kingdom – CE 0086
First Issued (Place/Date)	The United Kingdom, 8th February 2017
Applicable standards	See Technical File CEP2009005

Conformity assessment procedure per Article 11

Article 11 A or B	11A
Certificate n°	CE 651845
Notified Body (name/number/address)	BSI The united Kingdom – CE 0086
First Issued (Place/Date)	The United Kingdom, 8th june 2016

Australian Regulations:

This is a declaration of conformity made under clause 1.8 of Schedule 3 to the Therapeutic Goods (Medical Devices) Regulations 2002.
Each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied.

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

Authorised Signatory:

Kenneth Smith
International Quality Operations Manager
PO N.DELOCHE

44110 Châteaubriant - France
Place

20/11/2017
Date

05.INT.02	*Duration of archiving: End of life and support period*

List of Medline US finished products for declaration of conformity

Surgical gloves - Sensicare PI

DoC nr: DC Sensicar **Rev:** 01

Product number	Description	GMDN Code	Class	PPE Class
MSG9055	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9060	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9065	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9070	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9075	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9080	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9085	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III
MSG9090	Sensicare PI, Surgical glove, Sterile, Synthetic, Polyisoprene, Powder-Free	56293	IIa	III

*** GMDN code with description**

GMDN Code
56293 Polyisoprene surgical glove, non-powdered