



# Declaration of Conformity for Medline US products

**Declaration of conformity n°**  
**Revision n°**  
**Technical file #**

DC\_Triumph Classic  
03  
CE2017003 (MDD) and CEOP2015001 (PPE)

<b>Legal Manufacturer</b>	Medline Industries, Inc. Three Lake Drive, Northfield, Illinois 60093 USA
<b>EC Representative</b>	Medline International France SAS 5 rue Charles Lindbergh, 44110 Châteaubriant - France
<b>Product range</b>	Surgical Gloves – Triumph Classic
<b>Product codes</b>	See attached list
<b>Classification</b>	Medical Device class IIa Sterile - rule 6 Personal Protective Equipment Category III
<b>GMDN Codes</b>	47178 Hevea-latex surgical glove, non-powdered

## European Union Regulations:

<b>European Representative</b> 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.	
<b>Applicable directive:</b>	Medical Devices Directive: Council Directive 93/42/EEC of 14 June, 1993 as amended.
<b>Annex 93/42/EEC</b>	Annex II
<b>Notified Body</b>	BSI The united Kingdom – CE 0086
<b>Certificate n°</b>	CE 557201
<b>First Issued (Place/Date)</b>	The United Kingdom, 20 <sup>th</sup> January, 2010
<b>Applicable standards</b>	See Technical File CE2017003
<b>Applicable directive:</b>	Personal Protective Equipment: Council Directive 89/686/EEC of 21 December 1989.
<b>EC-type examination per Article 10</b>	
Certificate n°	CE 615803
Notified Body (name/number/address)	BSI The united Kingdom – CE 0086
First Issued (Place/Date)	The United Kingdom, 27 <sup>th</sup> August 2014
Applicable standards	See Technical File CEOP2015001
<b>Conformity assessment procedure per Article 11</b>	
Article 11 A or B	11B
Certificate n°	CE 51699
Notified Body (name/number/address)	BSI The united Kingdom – CE 0086
First Issued (Place/Date)	The United Kingdom, 17 <sup>th</sup> October 2012

## 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

44110 Châteaubriant - France

Place

20/11/2017  
Date

05.INT.02

Duration of archiving: End of life and support period

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List of Medline US finished products for declaration of conformity

FINT.491  
Revision n°00  
Effective date: 21 Oct 16  
Page 1 / 1

Surgical gloves - Triumph Classic

DoC nr: DC Triumph Rev: 03

Product number	Description	GMDN Code	Class	PPE Class
MSG5055	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5060	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5065	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5070	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5075	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5080	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5085	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III
MSG5090	Triumph® Classic Latex, Powder-Free, Surgical Gloves	47178	Ila	III

\* GMDN code with description

GMDN Code

47178 Hevea Latex, Surgical Gloves, non powdered