



Declaration of Conformity for Medline US products

Declaration of conformity n° DC267
Revision n° 07
Technical file # CE2011002

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	Suction tubing
Product codes	See attached list
Classification	Class I sterile- rule 1
GMDN Codes	16779 Suction system tubing; 42988 Low-pressure tubing connector Low-pressure tubing connector

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.	
General applicable directives:	Medical Devices Directive: Council Directive 93/42/EEC of 14 June, 1993 (MDD 93/42/EEC) as amended
Annex 93/42/EEC	V
Notified Body	BSI, The Netherlands – CE: 2797
Certificate n°	CE 555682
First Issued (Place/Date)	The United Kingdom, January 20, 2010
Applicable standards	See Technical File

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 declaration of conformity procedures applies, the production quality assurance procedures have also been applied. Each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures.

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

Authorised Signatory:

Kenneth Smith Digitally signed by Kenneth Smith
Date: 2020.06.05 14:38:40 +02'00'
Kenneth Smith
Senior QA/RA Manager

44110 Châteaubriant - France
Place

June 5th 2020
Date



Suction Tubing

DoC nr: DC267

Rev: 07

Product number	Description	GMDN Code	Class	PPE Class
DYND50221	Tubing,Suction,Connecting,3/16"X10',Str	16779	I	N/A
DYND50246	Tubing,Suction,Connecting,1/4"X6',Strl	16779	I	N/A
DYND50251	Tubing,Suction,Connecting,1/4"X10',Strl	16779	I	N/A
DYND50252	Suct Conn Tube 1/4" X 12' St	16779	I	N/A
DYND50253	Suct Conn Tube 1/4" X 20' St	16779	I	N/A
DYND50510	Connector,5-In-1,Sterile	42988	I	N/A
DYND50519	Connector,6-In-1 Y, Sterile	42988	I	N/A
ORNEX510	Suct.,Tube, 5mm,F/F+M,3mtr	16779	I	N/A
ORNEX56A	Suct.,Tube, 5mm,F/F+M, 1 80 Cm	16779	I	N/A
ORNEX56VC	Sterile suction tube with vacuum control	16779	I	N/A
ORNEX610	Suct.,Tube, 6mm,F/F+M,3 Mtr	16779	I	N/A
ORNEX66A	Suct.,Tube, 6mm,F/F+M, 1 80 Cm	16779	I	N/A
ORNEX66VC	Sterile suction tube with vacuum control	16779	I	N/A
ORNEX710	Tube,7mmx300cm,Non Con Duct W/Max Grip	16779	I	N/A
ORNEX712	Tube,7mmx360cm,Non Con Duct W/Max Grip	16779	I	N/A
ORNEX76A	Suct.,Tube, 7mm,F/F+M, 1 80 Cm	16779	I	N/A

* GMDN code with description

GMDN Code

16779 Suction system tubing

42988 Low-pressure tubing connector Low-pressure tubing connector