



Declaration of Conformity

Declaration of conformity n°
Revision n°
Technical file #

DC011
Rev.12
07

Manufacturer	Medline International France SAS 5 rue Charles Lindbergh 44110 Châteaubriant France	Single Registration Number of the Manufacturer	N/A
Product range	Non Sterile Bubble Suction Tubing		
Product codes	See attached reference list of catalog numbers and initial lot numbers		
Classification	Class I non-sterile, Rule 1		
GMDN codes	See attachment		

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 directive/regulation:	Medical Device Directive: Council Directive 93/42/EEC of 14 June, 1993 (MDD 93/42/EEC) as amended		
Conformity assessment procedure per MDD 93/42/EEC or MDR 2017/745	VII		
Notified Body	N/A		
Certificate n°	N/A		
First Issued (Place/Date)	N/A		
Applicable standards and/or Common Specifications	Listed in technical file # 07		

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.	

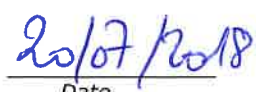
All supporting documentation is retained at the premises of the manufacturer.

Authorised Signatory:


Kenneth Smith
 International Quality Operations Manager

44110 Châteaubriant - France
Place


 P. N. DELOGE


 20/07/2018
 Date



List of finished products for declaration of conformity

FINT.434

Revision n°04

Effective date: 25 Sep 17

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Catalog number	GMDN code	Product description	MDD Class	PPE Class	First lot number CE
NBT5100	16779	NON STERILE BUBBLE SUCTION TUBING FOR UNIVERSAL CONNECTION - dia 5mm	I		250
NBT7100	16779	NON STERILE BUBBLE SUCTION TUBING FOR UNIVERSAL CONNECTION - dia 7mm	I		251
TUBVAC	16779	UNIVERSAL VACCUM CONNECTING WITH 40 MALE TUBING	I		

GMDN Code only for products classified as Medical devices.

16779	Suction system tubing
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