



Declaration of Conformity for Medline US products

Declaration of conformity n° DC216
Revision n° 12
Technical file # CES2005002

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 Face Masks
Product codes	See attached list
Classification	Class I Non-Sterile- rule 1
GMDN Codes	35177 Surgical face mask, single-use 11961 Shield, face

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 VII

Notified Body N/A

Certificate n° N/A

First Issued (Place/Date) N/A

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 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

03/04/2019
Date



List of Medline US finished products for declaration of conformity

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Surgical Face Masks

DoC nr: DC216

Rev: 12

Product number	Description	GMDN Code	Class	PPE Class
NON27120	Face Mask, Yellow, Earloop, Fiberglass Free, Latex Free	35177	I	
NON27361A	Face Mask, Anti Fog Aggressive Adhesive, Ties, Green, Fiberglass Free, Latex Free	35177	I	
NON27373A	Face Mask, Chamber Style, Anti Fog, Ties, Green, Fiberglass Free, Latex Free	35177	I	
NON27377	Face Mask, Blue, Tie On, Fiberglass Free, Latex Free	35177	I	
NON27378	Face Mask, Blue, Procedure, Earloop, Fiberglass Free, Latex Free	35177	I	
NON27385	Face Mask, White, Hypoallergenic, Ties, Fiberglass Free, Latex Free	35177	I	
NON27408	Face Mask, X-Tra Fluid Protection, Anti Fog, Ties, Blue, Fiberglass Free, Latex Free	35177	I	
NON27410	Face Mask, Fluid Resistant, Purple, Shield, Fog Free, Ties, Fiberglass Free, Latex Free	35177	I	
NON27410EL	Face Mask, Fluid Resistant, Purple, Shield, Fog Free, Earloop, Fiberglass Free, Latex Free	35177	I	
NON27412	Face Mask, Fluid Resistant, Purple, Fog Free, Ties, Fiberglass Free, Latex Free	35177	I	
NON27412EL	Face Mask, Fluid Resistant, Purple, Fog Free, Earloop, Fiberglass Free, Latex Free	35177	I	
NON27600	Surgical Face Mask, Horizontal Ties, Blue	35177	I	
NON27710	Face Mask, Max X Fluid Protection, Purple/White Pattern, Shield, Fog Free, Ties, Fiberglass Free, Latex Free	35177	I	
NON27710EL	Face Mask, Max X Fluid Protection, Purple/White Pattern, Shield, Fog Free, Earloop, Fiberglass Free, Latex Free	35177	I	
NON27712	Face Mask, Max X Fluid Protection, Purple/White Pattern, Fog Free, Ties, Fiberglass Free, Latex Free	35177	I	
NON27712EL	Face Mask, Max X Fluid Protection, Purple/White Pattern, Fog Free, Earloop, Fiberglass Free, Latex Free	35177	I	
NONFS300	Face Shield, Full Length, Foam Band, Fiberglass Free, Latex Free	11961	I	
NONFS400	Face Shield, 3/4 Length, Foam Band, Fiberglass Free, Latex Free	11961	I	

*** GMDN code with description**

GMDN Code
11961 Shield, face
35177 Mask, surgical, single-use

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Duration of archiving : End of life and support period

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