

Declaration of Conformity Certificate

We

Manufacturer: PRIMED Medical Products
Address: 200, 2003 – 91 St SW, Edmonton
 Alberta T6X 0W8, Canada
Phone Number: 1 877 877 4633
Single Registration Number: TBD

Declare with sole responsibility, that our product/s:

CND/ EMDN Code	CND/ EMDN Description	Product Code	Product Name	Classification Rationale per MDR (Annex VIII, Rule 1)
T020601	Standard Surgical Masks	Attached	Attached	Class I
T020602	Surgical Face Anti-Fog Masks	Attached	Attached	Class I
T020699	Surgical Face Masks - Other	Attached	Attached	Class I

meet, the general safety and performance requirements of Regulation (EU) 2017/745 pertaining to medical devices. Pathway of conformity per Article 19 and Annex IV.

Basic UDI-DI: 5391534520101PRCAN21KN

The product(s) identified above meet requirements of the Medical Devices Regulation by meeting the following standards

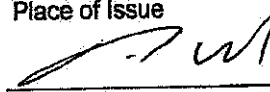
Standard No.	Standard Description
EN 14683:2019	Medical Face Masks – Requirements and Test Methods
ISO 13485:2016	Medical Devices – Quality Management System – Requirements for regulatory purposes

We hereby appoint mdi Europa GmbH, Langenhagener Str. 71, 30855 Langenhagen, Germany to act as European Authorized Representative as explicitly defined in Article 11 of Regulation (EU) 2017/745.

May 27, 2021
Date of Issue

Edmonton
Place of Issue


David Welsh
Printed Name


Signature

President & Chief Executive Officer
Title

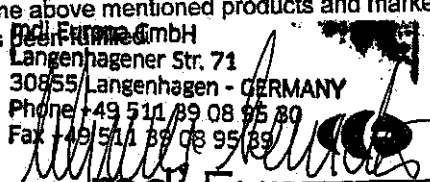

PRIMED Medical Products Inc.
Company

mdi Europa use only!

The necessary pre-requisites for placing the  mark on the above mentioned products and marketing them in all Member States of the European Union, have thus been fulfilled.

Signed this day _____ of _____ 20____

mdi Europa GmbH
 Langenhagener Str. 71
 30855 Langenhagen - GERMANY
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mdi Europa 
 CE-Marking Experts for Medical Devices

28. May 2021  Effective

SKU number	Description
6073310	Folitex® Tie-on Facemask, Blue
6073311	Folitex® Earloop Facemask, Blue
6073312	Folitex® Sensitive Tie-on Facemask, White
6073313	Folitex® Antifog Tie-on Facemask with Foam, Blue
6073314	Folitex® Antifog Tie-on Facemask with Foam, Green
6073315	Folitex®Anti-fog Earloop Facemask with Anti-fog Visor, Foam, Blue
6073316	Folitex® Anti-fog Tie-on Facemask with Anti-fog Visor, Foam, Blue
6073317	Folitex® Earloop Plus Facemask, Blue