

Declaration of Conformity Certificate

We

Manufacturer: PRIMED Medical Products Inc.
 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)
T0205	Non-Surgical Gowns	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: 5391534520201PRCAN21LK

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


Standard No.	Standard Description
ISO 13485:2016	Medical Devices – Quality Management System – Requirements for regulatory purposes
ISO 10993-5	Biological evaluation of medical devices – Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices – Tests for irritation and skin sensitization

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

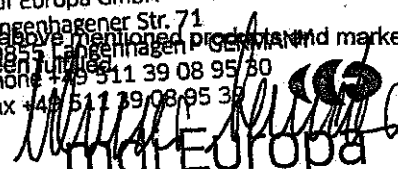

President & Chief Executive Officer
Title

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 01 of June 2021



mdi Europa
 CE-Marking Experts for Medical Devices

mdi Europa GmbH
 Langenhagener Str. 71
 30855 Langenhagen, Germany
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Effective

SKU number	Description
6072210	Folitex® Visitor Gown, Overhead, Green
6072211	Folitex® Visitor Gown, Tie Neck, Green
6072212	Folitex® Visitor Gown, Overhead, Blue
6072213	Folitex® Procedure Gown, Tie Neck, Yellow, 30G
6072214	Folitex® Procedure Gown, Tie Neck, Yellow, 40G
6072215	Folitex® Visitor Gown, Overhead, Yellow, 30G
6072216	Folitex® Procedure Gown, Overhead, Yellow, 40G

Effective