

EC Declaration of Conformity

Manufacturers Name:	Besmed Health Business Corp.
Manufacturers Address:	No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City, Taiwan 24888
SRN (Single Registration Number) of Manufacturer:	[TW-MF-000007246]
Authorized Representative Name (if applicable):	Mdi Europa GmbH
Authorized Representative Address	Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany
SRN (Single Registration Number) of Authorized Representative:	[DE-AR-000006218]
Basic UDI-DI:	4716770CP66240XX
Name of the Device Group (s):	CPR Pocket Mask
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R03020201
Conformity assessment route:	Conformity assessment based on a Quality Management System (Annex IX of MDR, Chapter 1 and 3), Production quality assurance (Annex XI of MDR) and technical documentation (Annex II & III of MDR).
Intended use:	Besmed CPR Mask is a non-invasive, non-prescription face shield with inflatable cuff and an integral non-rebreathing valve and hydrophobic filter. The face shield serves as physical barrier, intended to prevent direct mouth contact with patient's face when providing mouth-to-mouth resuscitation.
Classification:	CLASS I, rule 1
Harmonized standards or CS are applied:	EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 15223-1:2016

This declaration of conformity is issued under the sole responsibility of Besmed Health Business Corp. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by Besmed Health Business Corp. All supporting documentation is retained at the premises of the manufacturer.

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Signature:

 Handwritten signature in blue ink, appearing to be "Sarah Lu".

Sarah Lu

FUNCTION: Vice President

Place and date (yyyy.mm.dd) of issue:

New Taipei City, 2021.09.23

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Besmed Health Business Corp. RA CONFIDENTIAL 20210113

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Attachment to declaration of conformity [CPR Pocket Mask]

CPR Pocket Mask

Device	Reference number	Description
CPR Pocket Mask	CP-66240	CPR Pocket Resuscitator Set With Tube

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