

EC Declaration of Conformity

Manufacturers Name:	Besmed Health Business Corp.
Manufacturers Address:	No. 5, Lane 116, Wu-Kong 2 nd Road, Wu-Ku District, New Taipei City, Taiwan 24888
SRN (Single Registration Number) of Manufacturer:	TW-MF-000007246
Authorized Representative Name (if applicable):	Casus Europe B.V.
Authorized Representative Address	Lange Viestraat 2b, 3511 BK Utrecht, The Netherlands.
SRN (Single Registration Number) of Authorized Representative:	NL-AR-000037688
Basic UDI-DI:	4716770CP0600DR
Name of the Device Group (s):	CPR Mask
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R03010201
Conformity assessment route:	Conformity assessment based on a Declaration of Conformity and CE Marking of Conformity (Annex IX of Regulation (EU) 2017/745)
Intended use:	Besmed CPR Mask is intended to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation and acts as a barrier that will direct expired air from the patient away from the user. The Besmed CPR pocket mask is a pliable facial shield that features an air-cushioned cuff equipped with an oxygen port.
Classification:	CLASS I, Rule 2: Besmed CPR Mask is a non-invasive devices that is used to prevent direct mouth contact with the patient's face when providing mouth-to-mouth resuscitation.
Harmonized standards or CS are applied:	EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 20417:2021, IEC 62366-1:2015/AMD1:2020, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2023, EN ISO 10993-23:2021, EN ISO 18561-1:2020, EN ISO 18562-2:2020, EN ISO 18562-3:2020, EN ISO 15223-1:2021, ISTA 2A:2011, UL 969:2018, EN ISO 5356-1:2015, EN ISO 10651-4:2023.
CE certificate no.	N/A

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.

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

Place and date (yyyy.mm.dd) of issue: Taipei, 2025.07.14

Signature:

Sarah Lu

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Sarah Lu
Vice President
For and on behalf of Besmed

Steven Wong

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Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Attachment to declaration of conformity [CPR Mask]

CPR Mask

Device	Reference number	Description
CPR Pocket Resuscitator Set	CP-66230	CPR Pocket Resuscitator Set
	CP-66240	CPR Pocket Resuscitator Set W/Tube