

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, Utrecht, 3511 BK, The Netherlands.
SRN (Single Registration Number) of Authorized Representative:	NL-AR-000037688
Basic UDI-DI:	4716770RE02400G3
Name of the Device Group (s):	TEETH SCREW DRIVER
Product (MDN) code:	1201
European Medical Device Nomenclature (EMDN):	R03020201
Conformity assessment route:	Conformity assessment based on a Quality Management System, and technical documentation (Annex IX of MDR 2017/745).
Intended use:	Besmed Teeth Screw Driver is intended to open the mouth by rotating manner to provide the respiratory support to the patient.
Classification:	CLASS I, Rule 5: Besmed Teeth Screw Driver is an invasive devices intended to open the patient's mouth to establish the airway.
Harmonized standards or CS are applied:	EN ISO 13485:2016/AC:2018, EN ISO 14971:2019, EN ISO 24971:2020, EN ISO 20417:2020, 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 15223-1:2021, ISTA 2A:2011, ASTM F1980-21, EN ISO 10651-4:2023.

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.

EC Declaration of Conformity

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

Place and date (yyyy.mm.dd) of issue: Taipei, 2021.05.26

Signature:

Sarah Lu

.....

Sarah Lu
Vice President
For and on behalf of Besmed

Steven Wong

.....

Steven Wong
Regulatory Affairs Manager
For and on behalf of Besmed

Attachment to declaration of conformity [Teeth Screw Driver]

TEETH SCREW DRIVER

Device	Besmed Reference number	Description
Teeth Screw Driver	PO-85440	Teeth Screw Driver Small, White