

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:	4716770PO85440XX
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 (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:	The Teeth Screw Driver is intended for immediate break through on single tooth and or multiple tooth application supporting manual pulmonary resuscitation and emergency respiratory support. For use by CPR-trained personnel only, in hospital and pre-hospital settings.
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.

Signature:



Sarah Lu

FUNCTION: Vice President

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

New Taipei City, 2021.09.23

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Attachment to declaration of conformity [Teeth Screw Driver]

Teeth Screw Driver

Device	Reference number	Description
Teeth Screw Driver	PO-85440	Teeth Screw

Besmed Health Business Corp. RA CONFIDENTIAL 20210113