Number: 6170840CE01

EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

Manufacturer:

Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District,
New Taipei City 24888
Taiwan
SRN ID.: TW-MF-000007246

DEKRA grants the right to use the EC Notified Body Identification Number illustrated below to accompany the CE Marking of Conformity on the products concerned conforming to the required Technical Documentation and meeting the provisions of the EU- Regulation which apply to them:

0344

Supplement to certificate: 6092261CN

Authorized Representative: Mdi Europa GmbH
Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany

DEKRA hereby declares that the above mentioned manufacturer fulfils the relevant requirements of EU Regulation 2017/745, including all subsequent amendments for the above mentioned conformity assessment. The manufacturer/ authorized representative is subject to periodic surveillance required for the applicable conformity assessment in accordance to Regulation 2017/7

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Principal Certification Manager

First Issued: **1 February 2024** Date: **18 March 2024** Expiry date: **1 February 2029**

DEKRA Certification B.V. is Notified Body with ID no 0344

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 www.dekra.nl Company registration 09085396

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EU Quality Management System Certificate

Conformity Assessment Regulation 2017/745 on Medical devices, Annex IX Chapter I and III

This certificate covers the following device(s) / groups of device(s):

Non-active non-implantable devices for anaesthesia, emergency and intensive care (MDN 1201, class Is) Sterilization method: EtO
Device Name: Airway Management (Sterile)

Non-active non-implantable diagnostic devices (MDN 1207, class Im)
Group of Devices: Peak Flow Meter

Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis (MDN 1202, class IIa)
Device Name: Silicone drainage tube and reservoir (sterile)

Conditions for or limitations to the validity of this certificate:

- For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions
- For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements

Certificate History

Identification of the Common Specifications and Harmonized Standards complied with are documented within the technical documentation and audit assessments carried out. These are traceable through the DEKRA Certification B.V. Certification Notice. The Certification Notice also identifies the necessary information related to the quality management system of the manufacturer, including facilities.

Revision	Date of issue certificate	Certification Notice Reference	Action
0	1 February 2024	6092261CN05	first issue
1	18 March 2024	6092261CN06	revised

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