CERTIFICATE

Number: 6156705

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District
New Taipei City 24888
Taiwan

including the implementation meets the requirements of the standard:

ISO 13485:2016
EN ISO 13485:2016

Scope:
Design, Development, Manufacture, Servicing, Distribution and Sales of Sterile and Non-sterile Respiratory Care, Gastroenterological (Stomach Tubing and Gastrostomy Catheter), Urological (Urine Drainage System), Gynecological (Fetal Vacuum Cup), Surgery (Drainage System) Products and Physical Medicine (TENS and Heating Pad), Active Respiratory Devices (Humidification System, Nebulizer compressor)

Certificate expiry date: 16 November 2027
Certificate effective date: 16 November 2024
Certified since: 24 May 2023

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

Besmed Health Business Corp. CONFIDENTIAL

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed

MGMT. SYS. RvA C 589

DEKRA Certification B.V. Meander 1051, 6825 MJ Arnhem P.O. Box 5185, 6802 ED Arnhem, The Netherlands
T +31 88 96 83000 F +31 88 96 83100 www.dekra.nl Company registration 09085396

ADDENDUM

To certificate: 6156705

The management system of the organization(s) and/or location(s) of:

Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District
New Taipei City 24888
Taiwan

Certified organization(s) and/or locations:

Additional locations	Certification Scope / Activities
Besmed Health Business Corp. No.2, Lane 106, Wu-Kong 3rd Rd., Wu-Ku District, New Taipei City 24889, Taiwan	Design, Development, Servicing, Distribution and Sales of Sterile and Non-sterile Respiratory Care, Gastroenterological (Stomach Tubing and Gastrostomy Catheter), Urological (Urine Drainage System), Gynecological (Fetal Vacuum Cup) and Surgery (Drainage System) Products and Physical Medicine (TENS and Heating Pad), Active Respiratory Devices (Humidification System, Nebulizer compressor)
Besmed Health Business Corp. No. 42, Dapumeiyuanqu 3rd Rd., Dalin Township, Chiayi County 62255, Taiwan	Manufacture of Sterile and Non-sterile Respiratory Care, Gastroenterological (Stomach Tubing and Gastrostomy Catheter), Urological (Urine Drainage System), Gynecological (Fetal Vacuum Cup) and Surgery (Drainage System) Products

Addendum expiry date: 16 November 2027
Addendum effective date: 16 November 2024

Besmed Health Business Corp.
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