

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

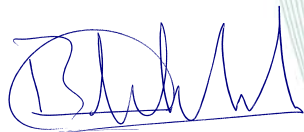
Scope:

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.

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



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

Besmed Health Business Corp.
No.2, Lane 106, Wu-Kong 3rd Rd., Wu-Ku District, New Taipei City 24889, Taiwan

Besmed Health Business Corp.
No. 42, Dapumeiyuanqu 3rd Rd., Dalin Township, Chiayi County 62255, Taiwan

Certification Scope / Activities

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)

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