



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
261946-2018-AQ-RGC-NA-PS

Initial certification date:
16 November 2018

Valid:
17 November 2021 – 16 November 2024

This is to certify that the management system of

Besmed Health Business Corp.

No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City 24888, Taiwan
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, 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), Physical Medicine (TENS and Heating Pad) and Surgery (Drainage System) Products.

Place and date:
Høvik, 02 November 2021



For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Lack of fulfillment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway - TEL: +47 67 57 99 00. www.dnv.com



Certificate no.: 261946-2018-AQ-RGC-NA-PS
Place and date: Høvik, 02 November 2021

Appendix to Certificate

Besmed Health Business Corp.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Besmed Health Business Corp.	No. 5, Lane 116, Wu-Kong 2nd Road, Wu-Ku District, New Taipei City 24888, 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 and Physical Medicine (TENS and Heating Pad).
Besmed Health Business Corp. - Wu-kong 3rd Rd.	No. 2, Lane 106, Wu-Kong 3rd Rd., Wu-Ku District, New Taipei City 24889, Taiwan	Design, 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), Physical Medicine (TENS and Heating Pad) and Surgery (Drainage System) Products.
Besmed Health Business Corp. - Chiayi	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.