DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 71794-2010-CE-RGC-NA
This Certificate consists of 4 pages

This is to certify that the Quality Management System of

Besmed Health Business Corp.

Taiwan

for design, production and final product inspection/testing of

Respiratory Care Products

has been assessed with respect to
the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:
Høvik, 22 June 2011

This Certificate is valid until:
31 March 2016

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY

NORWEGIAN ACCREDITATION
PROD 002

CE

Aud Løken Eiklid
Certification Manager

Notified Body No.:
0434

Mariann Jeremiassen
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info.

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as 'Forskrift for Medisinsk Utstyr' by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate 2006-OSL-MDD-0109	2006-03-31
	Recertification - new devices added	**2011-03-31**

Products covered by this Certificate

Product Description	Product	Class
Respiratory Care Products	- Bubble Humidifier - Jet Nebulizer Set - Peep Valve - Guedel Airway (Sterile) - Silicone Mask - Silicone Cushion Mask - Disposable Cushion Mask - Silicone Breathing Bag - Fatal Vacuum Cup - Silicone Drainage Tube & Reservoir (Sterile) - Silicone Stomach Tubing (Sterile) - Silicone Mask One Piece - Head Hardness - Laryngeal Airway Mask (Sterile) - Disposable Laryngoscope Set - Water Trap - Nasal Cannula - Hi-Oxygen Mask - Oxygen Mask - Oxygen Tubing - Aerosol Mask - Tracheotomy Mask - Face Tent - Artificial Nose - Venturi Mask - Breathing Circuit - Silicone T Tube (Sterile) - Silicone Penrose Tube (Sterile) - Bacterial Filter	IIa

Product Description	Product	Class
	- Humidification Chamber - Continous Positive Airway Pressure (CPAP) Mask - **Incentive Spirometer** - **Bag Valve Mask (BVM)**	

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate:

Site Name	Address
Legal Manufacture Besmed Health Business Corp.	No. 5, Lane 116, Wu-Kong 2nd Road., Wu-Ku District, New Taipei City 24888, Taiwan
Factory Ningbo Besmed Medical Equipment	No. 51, Mogan Shan Rd., Beilun, Ningbo, 315800, China

EU Representative:

Name	Address
Mdi Europa GmbH	Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany

Documents reviewed: TCF 007~035;038;040,TCF-041 and TCF-042

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE