

## EC DECLARATION OF CONFORMITY

For the following equipment:

### Anaesthetic Mask

- CM-65464 (57706) Disposable air cushion mask W/hook valve size#6 Adult extra large

(Product name, Type or Model, Designation)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the law of Member States concerning Medical Devices Directive (93/42/EEC-M5; 2007/47/EC) with the compliance of conformity assessment **Annex II excluding section 4** to be certified by DNV GL Nemko Presafe AS (Notify Body number 2460).

For the evaluation regarding the **Class IIa** product safety aspects, the following harmonized standards are applied:

**EN 1041:2008, EN ISO 15223-1:2016, EN ISO14971:2012, EN ISO13485:2016, EN ISO10993-1:2009/AC:2010, EN ISO10993-5:2009, EN 62366:2008**

the following non-harmonized standard are applied:

**ISO 10993-10:2010, ISO 5356-1:2015**

The following European Authorized Representative is stated to the declaration:

**Mdi Europa GmbH**

(Company Name)

**Langenhagener Str. 71, 30855 Hannover-Langenhagen, Germany**

(Company Address)

The following people is responsible for the compliance of declaration:

**Besmed Health Business Corp.**

(Name of Company)

**No. 5, Lane 116, Wu-kong 2nd Road, Wu-ku District, New Taipei City, Taiwan 24888**

(Company Address)



**BESMED HEALTH BUSINESS CORP.**

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

☎ : +886-2-2290-3959    📠 : +886-2-2299-9076  
✉ : info@besmed.com    🌐 : www.besmed.com

General Manager

\_\_\_\_\_  
(Position/Title)

A handwritten signature in blue ink, appearing to read "Bill Shyong", written over a horizontal line. The signature is stylized and cursive.

Bill Shyong  
\_\_\_\_\_  
(Legal Signature)

August 31, 2020

\_\_\_\_\_  
(Date)