

**EC DECLARATION OF CONFORMITY**

For the following equipment:

**FATAL VACUUM CUP**

**BE-0050 SILICONE VACUUM CUP, ID 50mm**  
**BE-0060 SILICONE VACUUM CUP, ID 60mm**  
**BE-0070 SILICONE VACUUM CUP, ID 70mm**

(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 o conformity assessment **Annex IX** to be certified by Det Norske Veritas (Notify Body number 0434)

For the evaluation regarding the **Class IIa** product safety aspects, the following harmonized standards are applied:  
**EN 1041:2008, EN 980:2008, EN ISO 10993-1:2009, EN ISO 10993-5:2009,**  
**EN ISO 10993-10:2009, EN ISO14971:2007**

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 2<sup>nd</sup> Road, Wu-Ku Industrial Park, Taipei Hsien, Taiwan**

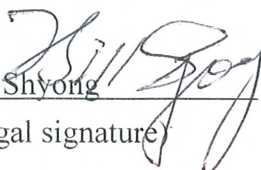
(Company Address)

General Manager

(Position/Title)

Bill Shyong

(Legal signature)



August 27, 2010

( Date)