BESMED HEALTH BUSINESS CORP.

NO. 5, LANE 116, WU-KONG 2nd RD., WU-KU INDUSTRIAL PARK, TAIPEI, TAIWAN
TEL: +886 2 2290 3959 FAX: + 886 2 2299 9076 www.besmed.com

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 2nd Road, Wu-Ku Industrial Park, Taipei Hsien, Taiwan
(Company Address)

General Manager	Bill Shyong	August 27, 2010
(Position/Title)	(Legal signature)	(Date)