

**EC DECLARATION OF CONFORMITY**

For the following equipment:

**LARYNGOSCOPE**

PN-1150 OPTIC HANDLE  
PN-1151 LARYNGOSCOPE FIBER OPTIC SET  
PN-11502 Disposable Fiber Optic McINTOSH Blade #4  
PN-11503 Disposable Fiber Optic McINTOSH Blade #3  
PN-11504 Disposable Fiber Optic McINTOSH Blade #2  
PN-11505 Disposable Fiber Optic Miller Blade #3  
PN-11506 Disposable Fiber Optic Miller Blade #2  
PN-11507 Disposable Fiber Optic Miller Blade #1  
PN-11508 Disposable Fiber Optic Miller Blade #0

(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 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)