



A DNV GL & NEMKO  
COMPANY

# Management System Certificate

Certificate No.: 248712-2017-AQ-RGC-NA-PS Rev. 1.0

Project No.: PRJ-C-50625-2008-MSC-TWN

Initial Certification Date: 01 NOVEMBER 2017

Valid Until: 08 JULY 2021

This is to certify that the management system of:

**Wellong Instruments Co., Ltd.**  
5th Fl., No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec. 2, Zhonghe Dist.  
New Taipei City  
Taiwan

With sites as listed overleaf.

Complies with the requirements of:

**ISO 13485:2016/NS-EN ISO 13485:2016**



The Certificate is valid for the following scope:

**Design, Manufacture, Sales, Servicing and Distribution of No-Sterile He-Ne Lasers, No-Sterile Spinal Fixation Systems and Sterile Shunting Systems**

Place and Date:  
Høvik, 16 June 2018

For:  
DNV GL NEMKO PRESAFE AS



**Tone Elise Kolpus**

*Tone Kolpus*

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.



# Management System Certificate

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Project No.: PRJC-50625-2008-MSC-TWN

Initial Certification Date: 01 NOVEMBER 2017

Site Name	Address	Site Scope
Wellong Instruments Co., Ltd. - Factory	5th Fl., No. 7, Alley 11, Lane 327, Zhongshan Rd., Sec. 2, Zhonghe Dist., New Taipei City, Taiwan	Design, Manufacture and Warehouse
Wellong Instruments Co., Ltd. - Taipei Office	2nd Fl., No. 63, Linsen N. Rd., Taipei, Taiwan	Sales and Purchase

End of Certificate





## CE DECLARATION OF CONFORMITY

For the following equipment:

WELLONG Shunting system (Trade Mark: BMI Medical)

(Product Name)

- Ventricular Catheter (01101, 01101T, 06115, 06115T, 06118, 06118S, 06118L, 06118L-1, 06118YS, 06118W, 21101, 21101T, 26115, 26115T, 26118, 26118S, 26118L, 26118L-1, 26118YS, 26118W)
- Peritoneal Catheter (Low, Medium, High, w/o pressure) (03103, 03103L, 03103M, 03103H, 03103T, 03103TL, 03103TM, 03103TH, 03105, 03105L, 03105M, 03105H, 03105T, 03105TL, 03105TM, 03105TH, 03107, 03107L, 03107M, 03107H, 03107T, 03107TL, 03107TM, 03107TH, 03109, 03109L, 03109M, 03109H, 03109T, 03109TL, 03109TM, 03109TH, 23103, 23103L, 23103M, 23103H, 23103T, 23103TL, 23103TM, 23103TH, 23105, 23105L, 23105M, 23105H, 23105T, 23105TL, 23105TM, 23105TH, 23107, 23107L, 23107M, 23107H, 23107T, 23107TL, 23107TM, 23107TH, 23109, 23109L, 23109M, 23109H, 23109T, 23109TL, 23109TM, 23109TH)
- CSF-Uni-Shunt (Low, Medium, High, w/o pressure) (05106, 05106L, 05106M, 05106H)
- Adjustable Delta Valve (05110~05146)
- Cement Vessel (02116 ~20 )
- Drug Port (04225, 04230)
- Skull nut (BN04, BN05, BN06, BN07, BN08, BN09, BN10, BN11, BN12, BN13, BN14, BN15, BN16)
- CSF-Flow Control Valve (Low, Medium, High, w/o pressure) (02314, 02314L, 02314M, 02314H, 02812, 02812L, 02812M, 02812H, 02912, 02912L, 02912M, 02912H, 04120, 04120L, 04120M, 04120H, 04115, 04124L, 04124M, 04124H, 04124, 22812, 22812L, 22812M, 22812H, 22912, 22912L, 22912M, 22912H, 24120, 24120L, 24120M, 24120H, 24115, 24124, 24124L, 24124M, 24124H)
- CSF-Ventricular Reservoir, Burr hole (Low, Medium, High, w/o pressure) (02512, 02512L, 02512M, 02512H, 02514, 02514L, 02514M, 02514H, 22512, 22512L, 22512M, 22512H, 22514, 22514L, 22514M, 22514H)
- CSF-Ventricular Reservoir, OMMAYA (04111, 04112, 04113, 04114, 04116, 04117, 04118, 04119, 04121, 04122, 04123, 04124, 04125, 04126, 04127, 08112, 08212, 08114, 08214)
- CSF-Catheter Connector, Straight (05103)
- CSF-Catheter Connector, Right Angle (05104)
- CSF-Catheter Connector, 3-Way (05105)
- Catheter Fixation Tab (06130, 06133, 06135)
- CSF Shunt System Kit (Low, Medium, High, w/o pressure) (07010, 07010L, 07010M, 07010H, 07020, 07020L, 07020M, 07020H, 07030, 07030L, 07030M, 07030H, 07050, 07050L, 07050M, 07050H, 07060, 07060L, 07060M, 07060H)
- Drainage Bag (06124)
- Patient Connection Line Assembly (06120, 06122, 06126)
- External Drainage and Monitoring System (EDMS) (06128, 06140, 06142)
- ICP Shunt Becker (06129)
- External Drainage and Monitoring System Kit (06138, 06148, 06158)





## CE DECLARATION OF CONFORMITY

- Bulb Drainage System (06648, 06648-1, 06648-2, 06648-3, 06648-4, 06648-5, 06648-6, 06648-10, 06648-11, 06648-12, 06648-13, 06648-14)
- Ventricular & Scope Cannular (R-2105, R-2105T)
- Disposable Tubing Set (US-62)

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(Model, Designation)

is herewith confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning **Medical Device Directive 93/42/EEC As Amended by 2007/47/EC** with the compliance the essential requirement – Annex I and the conformity assessment **Annex II** to be certified by DNV GL Nemko Presafe AS (notify body number – 2460).

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

EN 980 : 2008 / EN 1041 : 2008 / EN ISO 10993-1 : 2009 / EN ISO 10993-3/EN ISO 10993-5 : 2009 / EN ISO 10993-6 / EN ISO 10993-10/ EN ISO 10993-12 : 2009 / EN ISO 11135-1 : 2007 / EN ISO 11607-1 : 2009 / EN ISO 7197 : 2009 / EN ISO 14971 : 2009/EN1618/EN1617/ EN ISO 11737-1:2006/ AC:2009/ EN ISO 11737-2:2009

**The following European Authorized Representative is to the declaration:**

Y. Sung Handelsvertretung Duesselthaler Str.24 , 40211 Duesseldorf ,Germany  
(Company Name / Address)

**The following person is responsible for the compliance of declaration:**

WELLONG INSTRUMENTS CO., LTD. (Trade Mark: BMI Medical)  
2F, No.63, Linsen North Road, Taipei, Taiwan, R.O.C.  
(Manufacturer Name/ Address)

WELLONG INSTRUMENTS CO.,  
5<sup>th</sup> floor, No.7, Alley 11, Lane 327, Zhongshan Rd., Sec.2, Zhonghe Dist., New Taipei City,  
Taiwan, R.O.C.  
(Factory Name/Address)

General Manager  
(Position/ Title)

Robert W. H. Kuo  
(Legal Signature)

April 6, 2017  
(Date)

