Management System Certificate

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Initial Certification Date:	Valid Until:
248712-2017-AQ-RGC-NA-PS Rev. 1.0	**PRJC-50625-2008-MSC-TWN**	**01 NOVEMBER 2017**	**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

NORWEGIAN ACCREDITATION
MSYS 018

For:
DNV GL NEMKO PRESAFE AS

Tone Kolpus

Tone Elise Kolpus

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

CE
2460

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)

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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)

(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 Duesseldort ,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.,
5th 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)