MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:	Initial certification date:	Valid:
248712-2017-AQ-RGC-NA-PS rev.3.0	01 NOVEMBER 2017	16 JULY 2021 – 08 JULY 2024

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

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

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

This certificate is valid for the following scope:

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

Digitally signed by Iarovoi Petru
Date: 2021.12.20 12:11:16 EET
Reason: MoldSign Signature
Location: Moldova

Place and date:
Høvik, 16 July 2021

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Hazem Tinawi
Technical Reviewer

Certificate no.: 248712-2017-AQ-RGC-NA-PS rev.3.0
Place and date: Høvik, 16 July 2021

Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site 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

SAFEGUARDING LIFE, PROPERTY AND THE ENVIRONMENT - DNV 1864

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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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2460

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. Hsu (Legal Signature)

April 6, 2017 (Date)