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

EC Certificate
Full Quality Assurance System

Certificate No.:
9903-2017-CE-RGC-NA-PS

Project No.:
PRJC-50634-2008-PRC-TWN

Valid Until:
28 January 2024

This is to certify that the quality system of:

Wellong Instruments Co., Ltd.
5th Fl., No. 7, Alley 11, Lane 327, Zhong Shan Rd., Sec. 2, Zhonghe Dist., New Taipei City, Taiwan, R.O.C.

For design, production and final product inspection/testing of:

Shunting system

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 28 January 2019

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Palani Damodharan

The Certificate has been digitally signed.
See 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.

EC Certificate
Full Quality Assurance System

Certificate No.:
9903-2017-CE-RGC-NA-PS

Project No.:
PRJC-50634-2008-PRC-TWN

Valid Until:
28 January 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	28 January 2019

Products covered by this Certificate:

Product Description	Product Name		Class
Shunting system for ventricular procedure	Ventricular Catheter	06118, 06118S, 06118L, 06118L-1, 06118YS, 06118W, 26118, 26118S, 26118L, 26118L-1, 26118YS, 26118W	III
		01101, 01101T, 21101, 21101T	
		06115, 06115T, 26115, 26115T	
	Peritoneal Catheter (Low, Medium, High, w/o pressure)	03103(L, M, H), 03103T(L, M, H), 03105(L, M, H), 03105T(L, M, H), 03107(L, M, H), 03107T(L, M, H), 03109(L, M, H), 03109T(L, M, H), 23103(L, M, H), 23103T(L, M, H), 23105(L, M, H), 23105T(L, M, H), 23107(L, M, H), 23107T(L, M, H), 23109(L, M, H), 23109T(L, M, H)	

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
CSF-Flow Control Valve	02314(L, M, H), 02812(L, M, H), 02912(L, M, H), 04120(L, M, H), 04115, 22812(L, M, H), 22912(L, M, H), 24120(L, M, H), 24115
CSF-Ventricular Reservoir, Burr hole (Low, Medium, High, w/o pressure)	02512(L, M, H), 02514(L, M, H), 22512(L, M, H), 22514(L, M, H)
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
CSF Shunt System Kit (Low, Medium, High, w/o pressure)	07010(L, M, H), 07020(L, M, H), 07030(L, M, H), 07050(L, M, H), 07060(L, M, H)
Catheter Fixation Tab	06130, 06133, 06135
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
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
Skull nut	BN04, BN05, BN06, BN07, BN08, BN09, BN10, BN11, BN12, BN13, BN14, BN15, BN16
Ventricular & Scope Cannular	R-2105, R-2105T
Disposable Tubing Set	US-62

* Design assessment is covered by a separate EC-Design Examination Certificate No.: <12109-2018-CE-RGC-NA-PS >

Sites covered by this certificate

Site Name	Address
Wellong Instruments Co., Ltd. (manufacture and office)	2nd Fl., No. 63, Linsen N. Rd., Taipei, Taiwan, R. O. C.
Wellong Instruments Co., Ltd. (factory)	5th Fl., No. 7, Alley 11, Lane 327, Zhong Shan Rd., Sec. 2, Zhonghe Dist., New Taipei City, Taiwan, R. O. C.

EU Representative

Site Name	Address
Y. Sung Handelsvertretung	Duesselthaler Str. 24 40211 Duesseldorf Germany

EC Certificate
Full Quality Assurance System

Certificate No.: **9903-2017-CE-RGC-NA-PS**

Project No.: **PRJC-50634-2008-PRC-TWN**

Valid Until: **28 January 2024**

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

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)

CE
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)