EC Design Examination Certificate

Certificate No.:
12109-2018-CE-RGC-NA-PS

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

Valid Until:
28 January 2024

This is to certify that:

Shunting System

Manufactured by:

Wellong Instruments Co., Ltd.

Manufacture and office: 2nd Fl., No. 63, Linsen N. Rd., Taipei, Taiwan, R. O. C.
Factory: 5th Fl., No. 7, Alley 11, Lane 327, Zhong Shan Rd., Sec. 2, Zhonghe Dist., New Taipei City, Taiwan, R. O. C.

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 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

Digitally signed by Ermicev Alexandr
Date: 2019.12.03 13:06:04 EET
Reason: MoldSign Signature
Location: Moldova

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.

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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:

Type of medical device and identification no.:		Medical Device Class:	GMDN code:
Shunting system for ventricular procedure	Ventricular Catheter	III	45694, 47515, 10704
	Peritoneal Catheter (Low, Medium, High, w/o		
	CSF-Uni-Shunt (Low, Medium, High, w/o pressure)		
	Adjustable Delta Valve		
	Cement Vessel		
	Drug Port		
	CSF-Flow Control Valve		
	CSF-Ventricular Reservoir, Burr hole (Low, Medium, High, w/o pressure)		
	CSF-Ventricular Reservoir, OMMAYA		
	CSF-Catheter Connector ,Straight		
	CSF-Catheter Connector ,Right Angle		
	CSF-Catheter Connector ,3- Way		
	CSF Shunt System Kit (Low, Medium, High, w/o		
	Catheter Fixation Tab		36151, 10704
	Drainage Bag		
	Patient Connection Line Assembly		
	External Drainage and Monitoring System (EDMS)		
	ICP Shunt Becker		
	External Drainage and Monitoring System Kit		
	Bulb Drainage System		
	Skull nut		

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	Ventricular & Scope Cannular
	Disposable Tubing Set

Short description of the Medical Device:
Shunting system for ventricular procedure
Shunting System is designed to divert cerebrospinal fluid (CSF) from the ventricles of the brain to the right atrium of the heart or to the peritoneal cavity. This creates an alternative route for removal of CSF which is constantly produced within the brain and usually restores the physiological balance between CSF production, flow, and absorption when one or more of these functions has been impaired.
The shunting system is combination of devices used to divert fluid from the brain the ventricles of the brain into the peritoneal cavity. Components of a central nervous system shunt include Ventricular Catheter, Peritoneal Catheter, CSF-Uni-Shunt, Adjustable Delta Valve, Cement Vessel, Drug Port, Skull nut, CSF-Flow Control Valve, CSF-Ventricular Reservoir, CSF-Catheter Connector, and CSF Shunt System Kit; Catheter Fixation Tab, Drainage Bag, Patient Connection Line Assembly, External Drainage and Monitoring System (EDMS), ICP Shunt Becker, External Drainage and Monitoring System Kit, Bulb Drainage System, Skull nut, Ventricular & Scope Cannular, Disposable Tubing Set.
The CSF-Ventricular Catheters are available in 4 sizes and impregnated with white barium to provide radiopacity fully. The spherical tip of catheter is tantalum-impregnated. The graphitic markers are imprinted at 5, 10, and 15 cm from the catheter tip to show surgeons the depth of penetration of the catheter into the lateral ventricle. There are 4 rows with 4 holes in each row at the end of catheter tubing. The catheter is packaged with a stainless-steel stylet. The stylet facilitates insertion of the catheter into the lateral ventricle.

Sterilization by ethylene oxide gas.

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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 inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

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