EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 10731-2017-CE-KOR-NA-PS Rev. 2.0 Project No.: PRJC-40529-2007-MSL-KOR Valid Until: 27 May 2024

This is to certify that the quality system of:

Zerone Co., Ltd.

(Shinil IT UTO Bldg., Dangjeong-dong) #810, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea

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

Electrosurgical and Ultrasonic Surgical Units, Infusion Pumps, Suction-irrigation pumps, Electrocardiograph and Endoscopic electrosurgical electrode.

Has been assessed with respect to:

The conformity assessment procedure described in Annex II excluding section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Digitally signed by Bunic Gheorghe
Date: 2023.04.15 16:56:31 EEST
Reason: MoldSign Signature
Location: Moldova

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

Place and date:
Høvik, 29 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

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
0.0	Original Certificate	03 July 2017
1.0	Extension in scope - new products added (INFU-Z 2000)	24 September 2018
2.0	**Recertification**	**29 April 2021**

Products covered by this Certificate:

Product Description	Product Name	Class
Electrosurgical Unit	▪ ZEUS PRIME ▪ ZEUS VISION ▪ DOCTANZ TOUCH ▪ ACE VISION ▪ ZEUS-400 ▪ DOCTANZ400 ▪ ACE-400 ▪ ZEUS-300 ▪ DOCTANZ300 ▪ ACE-300 ▪ ZEUS-200S ▪ DOCTANZ200S ▪ ACE-200S ▪ ZEUS-200 ▪ DOCTANZ200 ▪ ACE-200 ▪ ZEUS-150 ▪ DOCTANZ150 ▪ ACE-150 ▪ ZEUS-100 ▪ DOCTANZ100 ▪ ACE-100 ▪ ZEUS-80 ▪ DOCTANZ80 ▪ ACE-80	IIb

	▪ ZERO50 ▪ SENS-Z ▪ ARGON-Z	
Ultrasonic Surgical Unit	▪ ULTRA-Z	IIb
INFUSION PUMP	▪ INFU-Z 1000 ▪ INFU-Z 2000 ▪ INFU-Z 4000	IIb
SYRINGE PUMP	▪ SYRIN-Z 4000	IIb
Endoscopic electrosurgical electrode, bipolar, reusable	▪ VS01-01R ▪ VS01-02R ▪ VS02-01R ▪ VS02-02R	IIb
SUCTION-IRRIGATION PUMP	▪ ZP-1000	IIa
ECG (electrocardiographs)	▪ CZ-800 ▪ CZ-430	IIa

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	**Address**
Zerone Co., Ltd.	(Shinil IT UTO Bldg., Dangjeong-dong) #810, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea

EU Representative

CMC Medical Devices & Drugs S.L. C/Horacio Lengo N° 18, CP 29006, Málaga, Spain

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. the Notified Body 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.

End of Certificate