



Declaration of Conformity



Manufacturer	ZERONE Co., Ltd.
Address	(Shinil IT UTO Bldg., Dangjeong-dong) 8F, LS-ro 13, Gunpo-si, Gyeonggi-do, 15843 Republic of Korea
Single Registration Number	KR-MF-000014148
EU Representative	CMC Medical Devices & Drugs S.L.
Address	C/Horacio Lengo N° 18, CP 29006, Málaga, Spain
Single Registration Number	ES-AR-000000293
Product	Endoscopic Electrosurgical Electrode, Bipolar, Reusable
Model Code	VS01-01R, VS01-02R, VS02-01R, VS02-02R
The Basic UDI	88094174200138J
Classification	Class IIb, Rule 9 according to Annex IX of the MDD
CE Certificate No.	10731-2017-CE-KOR-NA-PS Rev. 2.0
GMDN Code	61873

Is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC

Is in conformity with the applied standards EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 13485:2016/AC:2018, EN ISO 14971: 2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-10:2023, IEC 60601-2-2:2017, EN ISO 17665-1:2006, ISO/TS 17665-2:2009, EN 60068-2-31:2008, EN 60068-2-64:2008, MEDDEV.2.7.1 Rev.4

Is subject to the procedure set out in Annex II (excl. Section 4) of Directive 93/42/EEC as amended by 2007/47/EC under the supervision of Notified Body (CE 2460, DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway).

Manufacturer;

Date: August 16th, 2024

Position : Chief Executive Officer

Name : Yang Bae, Kim
