



# 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 **Electrosurgical Unit**  
Model Code **ZEUS PRIME**  
The Basic UDI **88094174200018B**

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 **44776**

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 60601-1:2006/A1:2013, EN 60601-1-2:2015, IEC62304:2006/A1:2015, EN IEC 60601-2-2:2018, ISO 17665-1:2006, ISO/TS 17665-2:2009, MEDDEV.2.7.1 Rev.4, EN 60068-2-31:2008, EN 60068-2-64:2008**

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 16<sup>th</sup>, 2024

Position : Chief Executive Officer

Name : Yang Bae, Kim

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