Manufacturer's Self-Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Zerone co., Ltd.
Manufacturer address and contact details	(Shinil IT UTO Bldg., Dangjeong-dong) 8F, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea Contact Person : Lee Jeong Hwan Email : facgen@01zeus.com Tel: +82-31-689-5605
Single Registration Number (SRN) (if available)	KR-MF-000014148

Authorised Representative name (if applicable)	CMC Medical Devices & Drugs S.L.
Authorised Representative address and contact details	Contact Person : Manuel Mateos Email : info@cmcmedicaldevices.com Tel: +34951214054
Single Registration Number (SRN) (if available)	ES-AR-000000293

Notified body name (if applicable)	DNV Product Assurance AS □ See attached schedule
Notified body number (if applicable)	NB 2460 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	10731-2017-CE-KOR-NA-PS Rev. 2.0 10000416114-PA-NA-KOR Rev.0.0

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

	□ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	27 May 2024 □ See attached schedule
End date of extended validity/transition period	31 Dec 2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

■ Expired/expires *after* 20 March 2023:

■ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

■ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

□ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

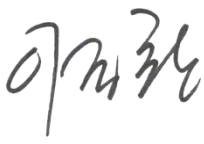
➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name : Zerone co., Ltd
Location & Date : (Shinil IT UTO Bldg., Dangjeong-dong) 8F, LS-ro 13, Gunpo-si, Gyeonggi-do, Korea / 07 Mar 2024

Signature, Print Name, Title : Lee Jeong Hwan / QMR



Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Electrosurgical Unit ▪ ZEUS PRIME /Basic UDI DI 88094174200018B	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Electrosurgical Unit ▪ ZEUS VISION ▪ DOCTANZ TOUCH ▪ ACE VISION /Basic UDI DI 88094174200028D	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Electrosurgical Unit ▪ ZEUS-400 ▪ DOCTANZ400 ▪ ACE-400 ▪ ZEUS-300 ▪ DOCTANZ300 ▪ ACE-300 ▪ ZEUS-200 ▪ DOCTANZ200 ▪ ACE-200 /Basic UDI DI 88094174200038F	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028

Electrosurgical Unit ▪ ZEUS-200S ▪ DOCTANZ200S ▪ ACE-200S ▪ ZEUS-150 ▪ DOCTANZ150 ▪ ACE-150 /Basic UDI DI 88094174200048H	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Electrosurgical Unit ▪ ZEUS-100 ▪ DOCTANZ100 ▪ ACE-100 ▪ ZEUS-80 ▪ DOCTANZ80 ▪ ACE-80 /Basic UDI DI 88094174200058K	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Electrosurgical Unit ▪ ZERO50 /Basic UDI DI 88094174200068M	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Electrosurgical Unit ▪ SENS-Z /Basic UDI DI 88094174200078P	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Argon plasma coagulator ▪ ARGON-Z /Basic UDI DI 88094174200088R	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028

INFUSION PUMP ▪ INFU-Z 1000 ▪ INFU-Z 2000 /Basic UDI DI 88094174200148L	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
INFUSION PUMP ▪ INFU-Z 4000 /Basic UDI DI 88094174200168Q	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
SYRINGE PUMP ▪ SYRIN-Z 4000 /Basic UDI DI 88094174200178S	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
SUCTUIN-IRRIGATION PUMPS ▪ ZP-1000 /Basic UDI DI 88094174200188U	IIa	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
ECG (electrocardiographs) ▪ CZ-800 ▪ CZ-430 /Basic UDI DI 88094174200198W	IIa	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Ultrasonic Surgical Unit ▪ ULTRA-Z /Basic UDI DI 88094174200108C	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028

Endoscopic electrosurgical electrode ▪ VS01-01R ▪ VS01-02R ▪ VS02-01R ▪ VS02-02R /Basic UDI DI 88094174200138J	IIb	N/A	10731-2017-CE-KOR-NA-PS Rev. 2.0 / NB 2460	27 May 2024	31 Dec 2028
Trocar ▪ZT-10, ZT-12F, ZT-20, ZT-22F, ZT-30, ZT-40 ▪ZTC-10, ZTC-30, ZTC-40 ▪ZT-10T, ZT-20T, ZT-30T, ZT-40T /Basic UDI DI 88094174200208F	IIa	N/A	10000416114-PA-NA-KOR Rev.0.0 / NB 2460	27 May 2024	31 Dec 2028