CU Medical Systems, Inc.

No. of Document: DOC-EU-SP2A (Rev.6)

Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer: CU Medical Systems, Inc.

130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Korea
Tel: +82 (0)33 747 7657
Fax: +82 (0)33 747 7659

EU Authorized Representative: Medical Device Safety Service, GmbH
Schiffgraben 41, 30175 Hannover, Germany

Notified Body: DNV Presafe AS CE2460

Certification No. 9805-2017-CE-KOR-NA-PS Rev. 6.0

Type of Product / Model / Classification:

Type of Product	Model No.	Classification
Defibrillator / monitor	**CU-SP2**	IIb, Rule 9 of Annex IX

EU Directive(s): 93/42/EEC concerning medical devices, as amended by 2007/47/EC

Conformity Assessment Route Annex II with the exemption of section 4

Declaration Statement:

We hereby declare that the above mentioned medical device(s) is(are) in conformity with applicable provisions of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices as amended by 2007/47/EC.

Date of Issue: May 11, 2021

Signature:

CU Medical Systems Inc.
Kim Hyung Soo
H. S. Kim / PRESIDENT

Hyungsoo, Kim, Chief Executive Officer

Annex I ; Declaration of Conformity Accessory List

*** Standard Accessories**

Disposable Defibrillation Pads (Adult/Pediatric)	CUA1007S
Rechargeable Battery Pack	CUA1802RB
Battery Adapter	K-820 Kkamnyng
Battery Charge Dock	CUA1207CH

*** Optional Accessories**

Carrying Case	SP2-A-BAG-3010
Disposable Battery Pack	CUCBM205B
Pediatric Pads	CUA1102S
Printer	SPP-R200
ECG Transmission Device	CU-EM1