CU Medical Systems, Inc.

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Medical Systems, Inc.

Document No.: DOC-EU-SP1

Declaration of Conformity

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer's Name	CU Medical Systems, Inc.
Manufacturer's Address:	130-1 Donghwagondan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365 Republic of Korea
EU Authorized Representative	Medical Device Safety Service, GmbH Schiffgraben 41, 30175 Hannover, Germany
Notified Body:	DNV GL Nemko Presafe AS CE2460
Type of Product:	Defibrillator
Model No.:	CU-SP1, CU-SP1 Plus
Battery Packs:	CUSA1103BB, CUSA1103BS
Defibrillation Electrodes:	CUA1007S, CUA1102S
Product Class:	IIb according to Rule 9 of Annex II of Council Directive 93/42/EEC
EU Directive	COUNCIL DIRECTIVE 93/42/EEC, as amended by 2007/47/EC

Declaration Statement
We, the manufacturer, hereby declare that the above mentioned medical device(s) is(are) in conformity with Annex II of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices as amended by 2007/47/EC

Date of Issue: July 5, 2017

Harock Na

HaRok Na
Chief Executive Officer