CU Medical Systems, Inc.

No. of Document: DOC-EU-HD(Rev.1)

Declaration of Conformity

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

Manufacturer:	CU Medical Systems, Inc.
(Address based on land lot numbers)	Donghwa Medical Instrument Complex 1647-1 Dongwha-ri, Munmak-eup, Wonju-si, Gangwon-do, 220-801 Republic of Korea
(Address based on road names and building numbers)	130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of Korea Tel: +82 33 747 7657 Fax: +82 33 747 7659
EU Authorized Representative:	Medical Device Safety Service, GmbH Schiffgraben 41, 30175 Hannover, Germany
Notified Body:	Nemko AS Gaustadalléen 30, N-0373 Oslo, Norway Identification no. 0470
Type of Product:	Defibrillators
Model No.:	CU-HD1
Classification:	Class IIb, according to Rule 9 of Annex IX of Directive 93/42/EEC
EU Directive(s):	93/42/EEC concerning medical devices, as amended by 2007/47/EC

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: August 30, 2016

Signature: HaRok Na, Chief Executive Officer

Digitally signed by Maxim Victor
Date: 2021.06.26 11:03:12 EEST
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