CU Medical Systems, Inc.

No. of Document: DOC-EU-CUP (Rev.2)

Declaration of Conformity

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

Manufacturer: CU Medical Systems, Inc.

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

Notified Body: DNV CE2460

Certificate No.: 9805-2017-CE-KOR-NA-PS Rev. 6.0

Product Description / Product Name / Class:

Product Description	Product Name	Class
Defibrillator	**CU-SP1, CU-SP1 PLUS, NF1201, NF1200, NFK200, CU-SP1 AUTO, CU-SPR, CU-SPX**	IIb
Defibrillator/monitor	**CU-HD1, CU-SP2**	IIb
Pediatric Defibrillation Electrode	**CUA0512P, CUA0711P, CUA0809PA, CUA1102S**	IIb
Defibrillation Electrode	**CUA0508O, CUA0512F, CUA0903PF, CUA1007S, CUA1904S**	IIb
Ambulatory electrocardiogram system	**EL1S**	IIa

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

Conformity Assessment Rou Annex II excluding section 4

Declaration Statement:

We, the manufacturer, 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: 2021.05.06

Signature:

CU Medical Systems Inc.
H. S. Kim PRESIDENT

Digitally signed by Maxim Victor
Date: 2023.05.01 14:59:13 EEST
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