



Medical Systems, Inc.

CU Medical Systems, Inc.

No. of Document: DOC-EU-CUP (Rev.0)

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

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 Route: Annex II excluding 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: 2021.05.03

CU Medical Systems Inc.


H. S. KIM PRESIDENT

Signature: _____