CU Medical Systems, Inc.

No. of Document: DOC-EU-CUP (Rev.3)

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 / Class / Product Name / UDI:

Product Description	Class	Product Name	UDI
Defibrillator	IIb	**CU-SP1**	8809435481000
	IIb	**CU-SP1 PLUS**	8809435480461
	IIb	**CU-SP1 AUTO**	8809435480485
	IIb	**NF1200**	8809435482014
	IIb	**NF1201**	8809435482038
	IIb	**NFK200**	8809435482021
	IIb	**CU-SPR**	8809435481161
Defibrillator/monitor	IIb	**CU-HD1**	8809435483011
	IIb	**CU-SP2**	8809435481017
Pediatric Defibrillation Electrode	IIb	**CUA0512P**	8809435482106
	IIb	**CUA0711P**	8809435480096
	IIb	**CUA0809PA**	8809435483035
	IIb	**CUA1102S**	8809435481048
Defibrillation Electrode	IIb	**CUA0508O**	8809435482632
	IIb	**CUA0512F**	8809435482090
	IIb	**CUA0903PF**	8809435482083
	IIb	**CUA1007S**	8809435481031
	IIb	**CUA1904S**	8809435481215
Ambulatory electrocardiogram system	IIa	**EL1S**	8809435489815

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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: 2022.04.04

Signature: