CU Medical Systems, Inc.

No. of Document: DOC-EU-HD(Rev.5)

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 GL Presafe AS CE2460

Certification No. 9805-2017-CE-KOR-NA-PS Rev. 3.0

Type of Product / Model / Classification:

Type of Product	Model No.	Classification
Defibrillator / monitor	**CU-HD1**	IIb, Rule 9 of Annex IX

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

Conformity Assessment Route Annex II with the exemption of 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: January 14, 2020

Digitally signed by Tutunaru Diana
Date: 2023.09.05 16:10:33 MSK
Reason: MoldSign Signature
Location: Moldova

Signature: Harkrork, Ra, Chief Executive Officer