CU Medical Systems, Inc.

130-1 Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do,
26365, Republic of Korea
Tel : +82 33 747 7657
FAX : +82 33 747 7659

Medical Systems, Inc.

Document No.: DOC-EU-SP1

Declaration of Conformity

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Manufacturer's Name	CU Medical Systems, Inc.
Manufacturer's Address:	130-1 Donghwagondan-ro, Munmak-eup, Wonju-si, Gangwon-do, 26365 Republic of Korea
EU Authorized Representative	Medical Device Safety Service, GmbH Schiffgraben 41, 30175 Hannover, Germany
Notified Body:	DNV GL Nemko Presafe AS CE2460
Type of Product:	Defibrillator
Model No.:	CU-SP1, CU-SP1 Plus
Battery Packs:	CUSA1103BB, CUSA1103BS
Defibrillation Electrodes:	CUA1007S, CUA1102S
Product Class:	IIb according to Rule 9 of Annex II of Council Directive 93/42/EEC
EU Directive	COUNCIL DIRECTIVE 93/42/EEC, as amended by 2007/47/EC

Declaration Statement
We, the manufacturer, hereby declare that the above mentioned medical device(s) is(are) in conformity with Annex II of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices as amended by 2007/47/EC

Date of Issue: July 5, 2017

Harock Na

HaRok Na
Chief Executive Officer

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
9805-2017-CE-KOR-NA-PS Rev. 3.0	PRJC-558665-2017-MSL-KOR	05 July 2022

This is to certify that the quality system of:

CU Medical Systems, Inc.

130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwon-do, Republic of Korea

For design, production and final product inspection/testing of:

Defibrillator, Defibrillator/monitor with defibrillation electrodes.

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 14 January 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Certificate No.:
9805-2017-CE-KOR-NA-PS Rev. 3.0

Project No.:
PRJC-558665-2017-MSL-KOR

Valid Until:
05 July 2022

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replace the Nemko certificate EU1110405 (NB0470) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460) issued after re-certification	05 July 2017
1.0	Model add	02 July 2018
2.0	Pediatric Defibrillation Electrode add (bold font)	17 May 2019
3.0	**Certificate no. 10770-2017-CE-KOR-NA-PS has been merged after the recertification audit completed**	14 January 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Defibrillator	▪ CU-SP1 ▪ CU-SP1 PLUS ▪ NF1201 ▪ NF1200 ▪ NFK200 ▪ **CU-SP1 AUTO**	IIb
Defibrillator/monitor	▪ CU-HD1 ▪ CU-SP2	IIb
Pediatric Defibrillation Electrode	▪ CUA0512P, ▪ CUA0711P, ▪ CUA0809PA ▪ **CUA1102S**	IIb
Defibrillation Electrode	▪ **CUA1007S**	**IIb**

The complete list of devices is filed with the Notified Body

Sites covered by this certificate

Site Name	Address
CU Medical Systems, Inc.	130-1, Donghwagongdan-ro, Munmak-eup, Wonju-si, Gangwondo, Korea

Certificate No.:	Project No.:	Valid Until:
9805-2017-CE-KOR-NA-PS Rev. 3.0	PRJC-558665-2017-MSL-KOR	05 July 2022

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

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate