EC CERTIFICATE
Full Quality Assurance System

Certificate No.: 9805-2017-CE-KOR-NA-PS Rev. 6.0 Project No.: PRJC-558665-2017-MSL-KOR Valid Until: 27 May 2024

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, and Ambulatory electrocardiogram system.

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

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

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

Place and date:
Høvik, 13 April 2021

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Mariann Jeremiassen
Principal Assessor

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 added	02 July 2018
2.0	Pediatric Defibrillation Electrode added	17 May 2019
3.0	Certificate no. 10770-2017-CE-KOR-NA-PS has been merged after the recertification audit completed	14 January 2020
4.0	Scope Extension for model added (CU-SPR, CU-SPX)	26 March 2020
5.0	Recertification	07 August 2020
6.0	**Scope Extension for new product added - Ambulatory electrocardiogram system: EL1S (in bold)**	**13 April 2021**

Products covered by this Certificate:

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	IIb

	▪ CUA1102S	
Defibrillation Electrode	▪ CUA0508O ▪ CUA0512F ▪ CUA0903PF ▪ CUA1007S ▪ CUA1904S	IIb
Ambulatory electrocardiogram system	▪ **EL1S**	**IIa**

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, Gangwon-do, Republic of Korea

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 the Notified Body of any intended updating of the quality system and the Notified Body 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. the Notified Body 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.

End of Certificate