CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU0601401
Order No.: 75844

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12th January 1995 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer:	CU Medical Systems Inc. Medical Instrument Industry Park, 1720-26, Taejang-dong, Wonju-si, Kangwon-do, Korea
Device category:	Defibrillators
GMDN Code:	11132
Models:	See Appendix 1 to this certificate
Risk class as defined by the manufacturer:	IIb
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC, with the exemption of section 4.
Date of audit:	2006-05-09/10
Date of the end of the validity:	2011-12-01
Nemko EC notification No.:	0470
Remarks:	This certificate replaces certificate EU0601401, issued 2006-11-06

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Date of issue: 2006-11-27

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2006-11-27

Signature: Arild R. Hansgård
Principal Engineer

CE 0470

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Manufacturer: CU Medical Systems Inc.
Medical Instrument Industry Park,
1720-26, Taejang-dong, Wonju-si,
Kangwon-do,
Korea

Device category: Defibrillators

Appendix 1, Page 1 of 1:

The certificate referred to above includes the following devices/models:

CU-ER1
CU-ER2
CU-ER3
CU-ER4
CU-ER5
NF1200

Date of issue: 2006-11-27

Signature: Frank Skarpsno

Date of verification: 2006-11-27

Signature: Arild R. Hansgård

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