CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1110406
Order No.: 189722

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 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. Donghwa Medical Instrument Complex, 1647-1 Dongwha-ri, Munmak-eup, Wonju-si,Gangwon-do 220-801 Republic of Korea
Device category:	Defibrillators
GMDN codes:	17882
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 last audit:	2010-09-20/21
Date of the end of the validity:	2016-11-01
Nemko EC notification No.:	0470

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: 2011-10-31

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-10-31

per
Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

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P.O. Box 73, Blindern	Gaustadalléen 30	www.nemko.com	+47 22 96 03 30	+47 22 960 550
N-0314 Oslo, Norway	Oslo		Enterprise number:	NO 9443522430

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1110406
Order No.: 189722

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex,
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillators

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following devices/models, with the brand name Paramedic:

CU-ER1

CU-ER2

CU-ER3

Date of issue: 2011-10-31

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-10-31

Per
Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1110407
Order No.: 189720

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 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. Donghwa Medical Instrument Complex, 1647-1 Dongwha-ri, Munmak-eup, Wonju-si,Gangwon-do 220-801 Republic of Korea
Device category:	Defibrillators
GMDN codes:	17882
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 last audit:	2010-09-20/21
Date of the end of the validity:	2016-12-01
Nemko EC notification No.:	0470

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: 2011-11-02

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-11-02

per
Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

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N-0314 Oslo, Norway

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CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1110407
Order No.: 189720

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex,
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillators

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model, with the brand name:
Paramedic :

CU-ER5

Date of issue: 2011-11-02

Frank Skarpsno

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-11-02

per Lene Markussen

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1111402
Order No.: 189723

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 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. Donghwa Medical Instrument Complex, 1647-1 Dongwha-ri, Munmak-eup, Wonju-si,Gangwon-do 220-801 Republic of Korea
Device category:	Defibrillators
GMDN codes:	17882
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 last audit:	2010-09-20/21
Date of the end of the validity:	2016-12-01
Nemko EC notification No.:	0470

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: 2011-11-03

Frank Skarpsno

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-11-03

Per Lene Martinsen

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1111402
Order No.: 189723

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex,
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillators

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model :

CU-HD1

Date of issue: 2011-11-03

Frank Skarpsno

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-11-03

Per Arne Martinsen

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

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Enterprise number:
NO 9443522430

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1111403
Order No.: 189721

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 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. Donghwa Medical Instrument Complex, 1647-1 Dongwha-ri, Munmak-eup, Wonju-si,Gangwon-do 220-801 Republic of Korea
Device category:	Defibrillators
GMDN codes:	47910
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 last audit:	2010-09-20/21
Date of the end of the validity:	2016-12-01
Nemko EC notification No.:	0470

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: 2011-11-03

Frank Skarpsno

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-11-03

Per Arne Martinsen

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1111403
Order No.: 189721

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex,
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillators

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model:

NF1200

Date of issue: 2011-11-03

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-11-03

Signature: per Arild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1106403
Order No.: 176071

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 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. Donghwa Medical Instrument Complex 1647-1 Dongwha-ri, Munmak-eup, Wonju-si,Gangwon-do 220-801 Republic of Korea
Device category:	Defibrillator
GMDN code:	47910
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 last audit:	2010-09-20/21
Date of the end of the validity:	2016-07-01
Nemko EC notification No.:	0470

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: 2011-06-22

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-06-22

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

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CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1106403
Order No.: 176071

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillator

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model:

CU-SP1

Date of issue: 2011-06-22

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-06-22

Signature: Árild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1112407
Order No.: 190849

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 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. Donghwa Medical Instrument Complex, 1647-1 Dongwha-ri, Munmak-eup, Wonju-si,Gangwon-do 220-801 Republic of Korea
Device category:	Defibrillators
GMDN codes:	47910
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 last audit:	2010-09-20/21
Date of the end of the validity:	2017-01-01
Nemko EC notification No.:	0470

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: 2011-12-14

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-12-14

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1112407
Order No.: 190849

Manufacturer: CU Medical Systems, Inc.
Donghwa Medical Instrument Complex,
1647-1 Dongwha-ri, Munmak-eup,
Wonju-si,Gangwon-do
220-801 Republic of Korea

Device category: Defibrillators

Appendix 1: Page 1 of 1.

The certificate referred to above includes the following device/model:

NF1201

Date of issue: 2011-12-14

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Date of verification: 2011-12-14

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

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