CE CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Nemko

Certificate No.: EU1203409
Order No.: 201640

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:	CP Medical, Inc. 803 NE 25th Avenue, Portland, OR 97232 USA
Device category:	Sutures
GMDN code:	See Appendix 1 to this certificate
Models:	See Appendix 1 to this certificate
Risk class as defined by the manufacturer:	III
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.
Date of audit:	2011-11-03
Date of the end of the validity:	2017-05-01
Remarks:	This certificate replaces certificate number EU1203409 issued 2012-05-02 due to added device models.
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: 2012-05-29

Signature: Ragnar Stranger Christiansen
Lead assessor

Date of verification: 2012-05-29

Signature: Arild R. Hansgård
Lead auditor /Principal Engineer

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Manufacturer: CP Medical, Inc.
803 NE 25th Avenue,
Portland, OR 97232
USA

Device category: Sutures

Appendix 1: Page 1 of 1

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

Device category	Model	GMDN code
Absorbable sutures	Visorb® (PGA) – xxxxA	13908
	Visorb® Quick (PGA) – VQxxxx	13908
	Monoswift® (PGCL) – Lxxxx	17246
	Mono-Dox® (PDO) – Mxxxx	16584
Nonabsorbable sutures	Polypro®(polypropylene) – xxxxP, LMxxxxP	13909
	Polybond® (polyester) – CPxxxxA	13906
	Monomid® (nylon) – xxxxM, xxxxB	38000
	Silk – xxxxS	13910
	CP-Fiber, PowerFiber™ (PET/PE)-CPF-xxxx	13907

Date of issue: 2012-05-29

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Lead assessor

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