CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU0704403
Order No.: 148498

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:	Brachytherapy Needles
GMDN code:	37944
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:	2009-11-17/18/19
Date of the end of the validity:	2014-05-01
Nemko EC notification No.:	0470
Remarks:	This certificate replaces certificate EU0704403, issued 2007-04-04

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: 2010-06-08

Signature: Arild R. Hansgård
Principal Engineer

Date of verification: 2010-06-08

Signature: Lene Martinsen
Principal Engineer

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

Device category: Brachytherapy Needles

Appendix 1: Page 1 of 1.

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

Revision of model designations per 2010-06-08:

Device Category:	**Model:**	**GMDN Code:**
Brachytherapy Needles, sterile	0135-XX-XX, 97-10XXX, CPPS-XXXXX, CPPS-XXXXX-X, CPPS-BT-XXXX, CPPS-BTY-XXXX, CPPS-MN-XXXX, CPPS-SQ-XXXX, CPPS-SQ-XXXXX, CPPS-SQ-XXXX-X, CPPS-SQ-XXXXX-X, CPPS-SQY-XXXX, CPPS-SQY-XXXXX, CPPS-SQY-XXXX-X, CPPS-SQY-XXXXX-X, CPPS-SQY-XXXXX-XX, FP-00XX, IAPS-1820X-X, RPLN-X, RPLN-X-X, RPLN-XX	37944
Brachytherapy Needles, non-sterile	CPPS-BT-XXXX-NS, CPPS-BTY-XXXX-NS, CPPS-SQ-XXXX-NS, CPPS-SQ-XXXXX-NS, CPPS-SQY-XXXX-NS, RPLN-X-NS, RPLN-XX-NS	

Date of issue: 2010-06-08

Signature: Arild R. Hansgård

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Signature: Lene Martinsen