CERTIFICATE OF CONFORMITY WITH EUROPEAN DIRECTIVE

Certificate No.: EU1206401
Order No.: 207197

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:	Needle guide for brachytherapy
GMDN code:	38426
Models:	Brachytherapy Grid : CPG-xxxx, CPG-xxx-xxx and CPG-xxx-xx-xxxx
Risk class as defined by the manufacturer:	Is
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC.
Date of audit:	2011-11-03
Date of the end of the validity:	2017-07-01
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: 2012-06-01

Signature: Ragnar Stranger Christiansen
Lead auditor /Principal Engineer

Date of verification: 2012-06-01

Signature: Arild R. Hansgård
Lead auditor / Principal Engineer

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