DECLARATION OF CONFORMITY

Application of Council Directive: 93/42/EEC, Annex V and Annex VII

In addition to providing the declaration required by the Council Directive 93/42/EEC as amended by Council Directive 2007/47/EC, this is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the devices stated.

Standards to which Conformity is Declared:

93/42/EEC, Annex V and ISO 13485:2003

Name of Manufacturer:	Coeur, Inc.
Address of Manufacturer:	100 Physicians Way, Suite 200 Lebanon, TN 37090 USA
Sole Agent:	Nemoto Kyorindo Co., Ltd. 2-27-20 Hongo Bunkyo-ku Tokyo 113-0033 Japan
Distributor:	MGT Nemoto International Ltd. Timmerik 2 3020 Herent Belgium
Authorized Representative:	Medicor Medical Supplies Timmerik 2 3020 Herent Belgium
Type of Equipment:	50mL Disposable CT/MR Syringes, 100mL and 200mL Clear, Disposable CT Syringes, 50mL/50mL MR Syringes, and CT Dual Packs.
Model Number:	SY-50, SYPET-100, C855-5101, C855-5102, C855-5106, SYPET-200, C855-5201, C855-5202, C855-5206, C855-5075, C855-5079, C855-5154, C855-5155, C855-5174, C855-5178, C855-5254, C855-5258, C855-5304, C855-5308, C855-5404, and C855-5408
Classification:	IIa
GMDN Code: **Term:**	15286 Syringe, angiographic
Production Quality Assurance Certificate:	
Assessment Body:	BSI
Certificate Number:	CE 01848

I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive and Standards.

Place: Lebanon, TN USA

Signed: _____
Quality & Regulatory Affairs

Date: December 13, 2010