

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 in the attached schedule.

Standards to which Conformity is Declared:

ISO 13485:2003, ISO 594, ISO 10993, and ISO 11135

Name of manufacturer:	Coeur, Inc.
Address of manufacturer:	209 Creekside Drive Washington, NC 27889 USA
Address of manufacturer regulatory office:	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:	Advena Ltd. Pure Offices, Plato Close, Warwick CV34 6WE, UK
EU Authorized Representative:	Advena Ltd. Pure Offices, Plato Close, Warwick CV34 6WE, UK
Type of Equipment:	Syringes and their Accessories for Nemoto Injectors: Low Pressure Tubing, High Pressure Tubing and 125mL and 150mL Disposable Angiographic Syringes for Nemoto Injectors, 50mL Disposable CT/MR Syringes, 100mL and 200mL Clear, Disposable, CT Syringes, 50mL/50mL MR Syringes, and CT Dual Packs for Nemoto Injectors
Classification:	IIa
Production Quality Assurance Certificate Assessment Body:	BSI Kitemark Court Davy Ave Knowlhill, Milton Keynes MK5 8PP
Certificate Number:	CE 01848

For Class IIa sterile: For each kind of medical device that is supplied sterile and to which the Conformity Assessment Procedures (not requiring assessment by Secretary) have been applied the Production Quality Assurance Procedures have also been applied. Each kind of medical device complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Syringes and their Accessories for Nemoto Injectors

Low Pressure Tubing

Model Number: C455-0060, C455-0061, C455-1500, C455-2101, C455-2151, C455-2601, C455-2622

GMDN Code: 44685
Term: Tubing, radiographic procedure

High Pressure Tubing

Model Number: C453-0601

GMDN Code: 44685
Term: Tubing, radiographic procedure

125mL and 150mL Disposable Angiographic Syringes for Nemoto Injectors

Model Number: SY-125 (C855-5125), C855-5150

GMDN Code: 15286
Term: Syringe, angiographic

50mL Disposable CT/MR Syringes, 100mL and 200mL Clear, Disposable, CT Syringes, 50mL/50mL MR Syringes, and CT Dual Packs for Nemoto Injectors

Model Number: SY-50 (C855-5050), SYPET-100 (C855-5100), C855-5101, C855-5102, C855-5106, SYPET-200 (C855-5200), C855-5201, C855-5202, C855-5206, C855-5059, 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

GMDN Code: 15286
Term: Syringe, angiographic

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

Place: Lebanon, TN USA

Signed: Priscilla Cline

Date: 2/15/18