CooperSurgical

Declaration of Conformity

Application of Council Directive(s):	Medical Device Directive 93/42/EEC
Standards to which Conformity is Declared:	EN ISO 13485, EN ISO 14971, EN ISO 15223-1, EN 1041, EN 980, EN 62366, EN 61010-1, EN 61010-2-101, DS/EN 61010-2-010, EN 60601-1-1-2, EN 61326-2-6, EN 62304, EN 13704
Manufacturer's Name:	CooperSurgical, Inc.
Manufacturer's Address:	95 Corporate Drive, Trumbull, CT 06611 USA
Manufacturing physical location:	Research Instruments Bickland Industrial Park, Falmouth, Cornwall TR11 4TA, UK
Authorized European Representative:	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
Notified Body:	BSI (British Standards Institute) Kitemark Court Davy Avenue, Knowlhill Milton Keynes, MK5 8PP United Kingdom
Type of Equipment:	IVF Incubators
Device classification per MDD 93/42/EEC:	Class IIa, Rule 9
Conformity Assessment:	Annex V & VII of MDD 93/42/EEC (CE 69386)
Model Numbers:	K22400-110, K22400-230, K22200-110, K22200-230, K59500, K60000 (Refer to page 2 for a list of the model names and corresponding model numbers)
Date of First Issue:	February 1, 2018

We hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s). We also declare conformity against the United Kingdom Statutory Instrument SI 1994/3017 as amended by SI 2002/618.

March 19, 2018
(Signature) (date)

J. Chris Jensen
(Full Name)

Sr. Director, Regulatory Affairs and Compliance
(Position)

Rev. A: Original Release – 01/26/2018
Signed DoC. 02/01/2018
Rev. B: Revised Conformity Assessment to Annex V & VII (CE 69386) – 02/12/2018
Rev. C: Add manufacturing physical location – 03/19/2018

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IVF Incubators

Model Number	Model Name
K22400-110	G185 Standard Incubator 110V
K22400-230	G185 Standard Incubator 230V
K22200-110	G185 SensorTech Incubator 110V
K22200-230	G185 SensorTech Incubator 230V
K59500	G210 InviCell Standard Incubator
K60000	G210 InviCell Plus Incubator

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