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 10993, EN ISO 11135, EN ISO 11607, ISO 14644, EN 868, EN 1041, EN ISO 14971, EN ISO 15223-1
Manufacturer's Name:	CooperSurgical, Inc.
Manufacturer's Address:	95 Corporate Drive, Trumbull, CT 06611 USA
Authorized European Representative:	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands
Notified Body:	BSI (British Standards Institute) NB number: 2797 Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands *Applies to Annex V Only*
Type of Equipment:	**THE RUMI® SYSTEM** – Uterine Manipulator-Injector Tips (RUMI® = **R**owden **U**terine **M**anipulator **I**njector)
Device classification per MDD 93/42/EEC:	Class IIa, Rule 5
Conformity Assessment:	Annex V and Annex VII of MDD 93/42/EEC (CE 69386)
Model Numbers:	UMW676, UMB678, UMG670, UML516, UMO672, UMY514 (refer to Page 2 for device descriptions)
Date of First Issue:	August 31, 2004

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.

Rev. K: Update Rev. J history content – "Moved UMH600 and UMH650 Class IIa devices". Added quantity/box in Device Descriptions on Page 2. – 3 August 2015
Rev. L: Added reference to Annex VII in addition to Annex V in the Conformity Assesment. – 1 March 2016
Rev. M: Update Emergo address, remove Annex VII (inadvertently added) – 06/26/2017
Rev. N: Reinstate Annex VII in addition to Annex V in the Conformity Assessment.
Rev. O: Add Notified Body number 0086 and CE certificate number. 06/29/2018
Rev. P: Change BSI Notified Body from UK to The Netherlands. Add "*Applies to Annex V Only.*" – 02/25/2019

Feb. 26, 2019
(Signature) (date)

J. Chris Jensen
(Full Name)

Senior Director, Regulatory Affairs and Compliance
(Position)

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Disposable Uterine Manipulator Tips (Sterile)

Ref. Number	Color	Description
UMW676	White	The RUMI System® Disposable Uterine Manipulator Tip (Tip Diameter: 6.7 mm, Tip Length: 6 cm) Quantity: 5 per box
UMB678	Blue	The RUMI System® Disposable Uterine Manipulator Tip (Tip Diameter: 6.7 mm, Tip Length: 8 cm) Quantity: 5 per box
UMG670	Green	The RUMI System® Disposable Uterine Manipulator Tip (Tip Diameter: 6.7 mm, Tip Length: 10 cm) Quantity: 5 per box
UML516	Lavender	The RUMI System® Disposable Uterine Manipulator Tip (Tip Diameter: 5.1 mm, Tip Length: 6 cm) Quantity: 5 per box
UMO672	Orange	The RUMI System® Disposable Uterine Manipulator Tip (Tip Diameter: 6.7 mm, Tip Length: 12 cm) Quantity: 5 per box
UMY514	Yellow	The RUMI System® Disposable Uterine Manipulator Tip (Tip Diameter: 5.1 mm, Tip Length: 3.75 cm) Quantity: 5 per box

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