

Declaration of Conformity

Application of Council Directive(s): Medical Device Directive 93/42/EEC

Standards to which Conformity is Declared: ISO 13485, ISO 10993, ISO 11135, ISO 11607, ISO 14644, EN 1041, ISO 14971, BS EN ISO 15223

Manufacturer's Name: Cooper Surgical, 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: Intrauterine Insemination Catheter

Conformity Assessment: Annex V and Annex VII of MDD 93/42/EEC (CE 69386)

Device classification per MDD 93/42/EEC: Class I Sterile, Rule 5

Model Numbers: 7033, SM400, SM507, SM610, AIC18

Date of First Issue: October 30, 2007

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.

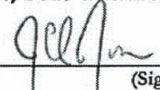
Rev. F: Update Emergo address, expand to list Model Numbers and Device Description on Page 2, update J. C. Jensen's position status to Senior – 06/26/2017

Rev. G: Added reference to Annex VII in addition to Annex V in the Conformity Assessment – 08/30/17

Rev. H: Added part number AIC18 – 06/19/18

Rev. I: Add Notified Body number 0086 and CE certificate number. 06/29/2018

Rev. J: Change BSI Notified Body from UK to The Netherlands. Add "Applies to Annex V Only." – 02/25/2019

 2/27/2019
(Signature) (Date)

J. Chris Jensen
(Full Name)

Senior Director, Regulatory Affairs & Compliance
(Position)

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SAO Y BẢN CHÍNH



Le Ngọc Thanh



Model Number	Model Name
7033	Uni-Sem Intrauterine Catheter – QTY 1 Box (25 Units)
SM400	Select IUI Intrauterine Catheter – QTY 1 Box (25 Units)
SM507	The Curve Intrauterine Insemination Catheter – QTY 1 Box (25 Units)
SM610	MiniSpace IUI Intrauterine Insemination Catheter – QTY 1 Box (25 Units)
AIC18	Wallace Intra-uterine Insemination Catheters – QTY 1 Box (10 Units)

