

# 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. **SAO Y BẢN CHÍNH**

**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)

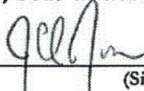
**Device classification per MDD 93/42/EEC:** Class I Sterile, Rule 5

**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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*Le Ngọc Thanh*



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## Intrauterine Insemination Catheter

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)

