

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, EN ISO 14644, EN 868, EN 1041, EN ISO 14971, EN ISO 15223, EN ISO 11737

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: Endometrial Suction Curette

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: MX140, MX145, MX150 (Refer to page 2 for details)

Date of First Issue: April 27, 2005

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.

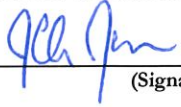
Rev. F: Update to Standards; update position; add Page 2 Model descriptions

Rev. G: Update Emergo address, specify model number details – 06/26/2017

Rev. H: Added reference to Annex VII in addition to Annex V in the Conformity Assessment.

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
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(Position)

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Pipet Curet™ Endometrial Suction Curette

Part Number	Description
MX140	3 mm (50/Box) – Greater integrity for stenotic Os
MX145	3 mm Soft Yellow (50/Box) – Pliable for molding catheter
MX150	4 mm (50/Box) – Multiparous patient