

# 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 ISO 14971, EN 868, EN 1041, EN 980, EN ISO 105223-1

**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:** Vacuum Assisted Delivery Devices and Accessories

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


**Device classification per MDD 93/42/EEC:** Class IIa, Rule 6

**Model Numbers:** 10004, 10007LP, 10008, 10015LP, 10020, 10021, 10137, 10500, 10022, 10057, 10058, 10067, 10068

**Date of First Issue:** February 19, 2004

***We hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).***

Rev. H: Update Standards. Added P/Ns: 10067 and 10068. Update J. Chris Jensen's position title to Senior level. (10/25/2016)  
Rev. I: Update Standards, update EMERGO address, expand to list Model Numbers and Descriptions on Page 2. (5/22/2017)  
Rev. J: Adjust Font Sizing (06/19/2017)  
Rev. K: Reinstate Annex VII in addition to Annex V in the Conformity Assessment. 8/28/2017  
Rev. L: Add Notified Body number 0086 and CE certificate number. 06/29/2018  
Rev. M: Change BSI Notified Body from UK to The Netherlands. Add "Applies to Annex V Only." – 02/25/2019  
Rev. N: Removal of ISO 11137. – 10/14/2019

 Oct. 14 2019  
(Signature) (date)

J. Chris Jensen  
(Full Name)

Senior Director, Regulatory Affairs and Compliance  
(Position)

**Vacuum-Assist Delivery Devices and Accessories**

**Cooper Surgical, Inc. 95 Corporate Drive, Trumbull, CT 06611 USA**

**Phone: (203) 601-5200 Fax: (203) 601-9870**

# Declaration of Conformity

Model Number	Model Name
10004	Mityvac® Pearl Edge® Bell Cup, Sterile Quantity: 1 Box (12 Units)
10007LP	Mityvac® M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10008	Mityvac® Super M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10015LP	Mityvac® M-Style® Mushroom Cup with Universal Vacuum Release (UVR) , Sterile Quantity: 1 Box (12 Units)
10020	Mityvac® MitySoft® Bell Cup, Sterile Quantity: 1 Box (12 Units)
10021	Mityvac® MitySoft® Bell Cup with Universal Vacuum Release (UVR) , Sterile Quantity: 1 Box (12 Units)
10137	Mityvac® M-Select® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10500	Mityvac® Reusable Vacuum Extraction Cup, Non-sterile Quantity: 1
10022	Mityvac® Reusable Obstetrical Vacuum Pump, Non-sterile Quantity: 1
10057	Mystic® II Mityvac® M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10058	Mystic® II Mityvac® MitySoft® Bell Cup, Sterile Quantity: 1 Box (12 Units)
10067	MityOne® Pump with M-Style® Mushroom Cup, Sterile Quantity: 1 Box (12 Units)
10068	MityOne® Pump with MitySoft® Bell Cup, Sterile Quantity: 1 Box (12 Units)