

# 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, ISO 11137, 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)  
Kitemark Court  
Davy Avenue, Knowlhill  
Milton Keynes, MK5 8PP  
United Kingdom

**Type of Equipment:** Vacuum Assisted Delivery Devices and Accessories

**Conformity Assessment:** Annex V 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). We also declare conformity against the United Kingdom Statutory Instrument SI 1994/3017 as amended by SI 2002/618.*

Rev D : July 21, 2011 Changed BSi Address; changed declaration language from individual to company ("I" to "We"); added document ID number

Rev. E: Mar 15, 2012 Add Conformity Assessment Annex V

Rev. F: Jul 1, 2013 Change BSI address

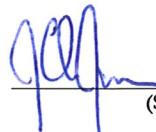
Rev. G: Changed Community Rep from Leisegang to Emergo Europe & removed 10007 & 100015

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

 Aug. 29, 2017  
(Signature) (date)

J. Chris Jensen  
(Full Name)

Senior Director, Regulatory Affairs and Compliance  
(Position)

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## Vacuum-Assist Delivery Devices and Accessories

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)