

Declaration of Conformity

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

Standards to which Conformity is Declared: BS EN ISO 13485, BS EN 10993-1, BS EN 14971, BS EN 1041, BS EN ISO 15223-1

Manufacturer's Name: CooperSurgical, Inc. also trading as Wallach Surgical Devices

Manufacturer's Address: 95 Corporate Drive, Trumbull, CT 06611 USA

Authorized European Representative: EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Type of Equipment: Cervical Cell Collector

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


Conformity Assessment: Annex VII of MDD 93/42/EEC

Model Numbers: 908001, 908002, 908003, 908003-2, 908003-3, 908004, 908006
(Refer to page 2 for details)

Date of First Issue: July 26, 2010

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

Rev. B Aug 24, 2011 Removed references to notified body and conformity assessment; changed declaration language from individual to company ("I" to "We"); added document ID number and revise AER to include name
Rev. C: Mar 1, 2012 Add Notified Body
Rev. D: March 01, 2012 Add Conformity Assessment Annex VII
Rev. E: July 01, 2013 Change BSI address
Rev. F: Oct. 07, 2014 Updated Standards List, Manufacturer name and EU Rep
Rev. G: Update Emergo address, expand Model Numbers and Device Description on Page 2, update J.C. Jensen's title to Senior status - 06/20/2017
Rev. H: Update product descriptions on page 2. Correct/Specify quantity description - 01/09/2018
Rev. I: Add P/Ns 908003-2 & 908003-3. Remove declaration to UK SI 1994/3017

 June 20, 2019
(Signature) (Date)

J. Chris Jensen
(Full Name)

Sr. Director, Regulatory Affairs & Compliance
(Position)

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Cervical Cell Collector

Model Number	Model Name
908001	Cervical Cell Sampler – QTY 100 per Bag
908002	Papette – QTY 5 per Bag
908003	Cervical Cell Sampler – QTY 1,000 per Box, 10 Bags of 100
908003-2	Cervical Cell Sampler – QTY 1,000 per Box, 40 Bags of 25
908003-3	Cervical Cell Sampler – QTY 1,000 per Box, 25 Bags of 40
908004	Cervical Cell Sampler – QTY 4,000 per Box, 40 Bags of 100
908006	Papette – QTY 500 per box, 20 Bags of 25