

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 14971, EN ISO 11135, ISO 11607, EN ISO 10993, EN ISO 14644, EN ISO 15223-1, EN 1041, EN 980, EN 62366

Manufacturer's Name: CooperSurgical, Inc., also trading as Lone Star Medical Products

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: Sterile Retractors

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 1

Model Numbers: 3301G, 3302G, 3304G, 91167709-01, 3307G, 3308G, 3309G, 3310G, 3715

Date of First Issue: February 1998 (Transfer from SGS)

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 G: Added part number 91167709-01 (p/n configuration to existing p/n 3304G). (3/07/2017)

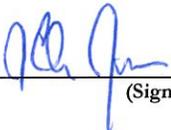
Rev. H: Update Emergo address, add 3309G to Model Numbers on Page 1 – 06/21/2017

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

Rev. J: Add Notified Body number 0086 and CE certificate number. 06/29/2018

Rev. K: Update Standards; Update rule classification to Rule 1; reference BSI certification only applies with conformance to Annex V. 10/30/2018

Rev. L: Change BSI Notified Body from UK to The Netherlands. – 02/25/2019

 2/27/2019
(Signature) (Date)

J. Chris Jensen
(Full Name)

Sr. Director, Regulatory Affairs & Compliance
(Position)

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LoneStar Retractor Rings Sterile, Disposable

Model Number	Model Name
3301G	Lone Star Disposable Retractor Ring, 25.3 cm x 11.3 cm – Qty 1
3302G	Lone Star Disposable Retractor Ring, 22.0 cm x 11.3 cm – Qty 1
3304G	Lone Star Disposable Retractor Ring, 32.5 cm x 18.3 cm, with (2) Catheter Clips – Qty 1
91167709-01	Lone Star Disposable Retractor Ring, 32.5 cm x 18.3 cm, with (2) Catheter Clips – Qty 1
3307G	Lone Star Disposable Retractor Ring, 14.1 cm x 14.1 cm – Qty 1
3308G	Lone Star Disposable Retractor Ring, 28.3 cm x 18.3 cm, with (2) Catheter Clips – Qty 1
3309G	Lone Star Disposable Retractor Ring, 18.6 cm x 8.9 cm – Qty 1
3310G	Lone Star Disposable Retractor Ring, 25.0 cm x 25.0 cm – Qty 1
3715	Lone Star APS Retractor Ring, Disposable, 16.6 cm x 16.6 cm with (2) Catheter Clips – Qty 1