

Declaration of Conformity

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

Standards to which Conformity is Declared: ISO 13485, EN 1041, ISO 14971, ISO 11135, ISO 11607, ISO 10993-5, ISO 10993-7, ISO 15223-1

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 Stays

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

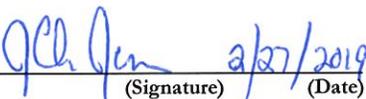
Device classification per MDD 93/42/EEC: Class IIa, Rule 6

Model Numbers: Refer to page 2 for a list of the model names and corresponding model numbers

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 F: 2 Sept 2015: Update C.Jensen Position & model numbers
REV G: Added reference to Annex VII in addition to Annex V in the Conformity Assessment. (02/03/2016)
REV H: Added part number 91167705-01 (p/n configuration to existing p/n 3350-8G). Remove Annex VII in the Conformity Assessment. (3/07/2017)
REV I: Update Emergo address – 06/21/2017
REV J: Reinstate Annex VII in addition to Annex V in the Conformity Assessment. 8/28/2017
REV K: Add Notified Body number 0086 and CE certificate number. 06/29/2018
REV L: Change BSI Notified Body from UK to The Netherlands. Add "*Applies to Annex V Only.*" – 02/25/2019


(Signature) (Date)

J. Chris Jensen
(Full Name)

Sr. Director, Regulatory Affairs & Compliance
(Position)

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LoneStar Sterile Stays

Model Number	Model Name
3311-1G	Lone Star Elastic Stays – 5 mm – Sharp Hook – 50 per case
3311-8G	Lone Star Elastic Stays – 5 mm – Sharp Hook – 8 per pack
3314-1G	Lone Star Elastic Stays – 3 mm – Sharp Hook – 50 per case
3314-8G	Lone Star Elastic Stays – 3 mm – Sharp Hook – 8 per pack
3325-4G	Lone Star Elastic Stays – Sharp Hook – 2-Finger – 5 mm Spread – 4 per pack
3327-4G	Lone Star Elastic Stays – Sharp Hook – 2-Finger – 7 mm Spread – 4 per pack
3329-4G	Lone Star Elastic Stays – Sharp Hook – 2-Finger – 9 mm Spread – 4 per pack
3331-4G	Lone Star Elastic Stays – 13 mm x 20 mm – Spira Solid Blade – 4 per pack
3330-4G	Lone Star Elastic Stays – 13 mm x 16 mm – Solid Blade – 4 per pack
3332-4G	Lone Star Elastic Stays – 14 mm x 16 mm – 2-Finger – 4 per pack
3333-4G	Lone Star Elastic Stays – 14 mm x 20 mm – Spira 2-Finger – 4 per pack
3334-4G	Lone Star Elastic Stays – 20 mm x 16 mm – 4-Finger – 4 pack
3335-4G	Lone Star Elastic Stays – 20 mm x 20 mm – Spira 3-Finger – 4 per pack
3338-4G	Lone Star Elastic Stays – 6.5 mm x 16 mm – Solid Blade – 4 per pack
3350-1G	Lone Star Elastic Stays – 12 mm – Blunt Hook – 50 per case
3350-8G	Lone Star Elastic Stays – 12 mm – Blunt Hook – 8 per pack
91167705-01	Lone Star Elastic Stays – 12 mm – Blunt Hook – 8 per pack
3350L-4G	Lone Star Elastic Stays – 12 mm – Blunt Hook – Long Stay – 4 per pack
3384-4	Lone Star Elastic Stays – 12 mm – 2-Finger Blunt Hook – 4 per pack
3550-1G	Lone Star Elastic Stays – 12 mm – Blunt Hook – 50 per case
3316-1G	Lone Star Elastic Stays – 5 mm – Blunt Hook – 50 per case
3316-8G	Lone Star Elastic Stays – 5 mm – Blunt Hook – 8 per pack
3205-8G	Lone Star Elastic Stays – 5 mm – Semi-blunt Pro-Stay – 8 per pack
3650	Lone Star Scroto-Pak™ (8) 12 mm Blunt Stays – (1) 5 mm Sharp Stay (1) Support Stay
3611	Lone Star Scroto-Pak™ (8) 5 mm Sharp Stays – (1) Support Stay