



Product Service

# EC Certificate

## Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 14 06 57666 045

### Manufacturer:

**Ethicon Endo-Surgery, LLC**

475 Calle C  
00969 Guaynabo  
PUERTO RICO USA

### EC-Representative:

**Ethicon Endo-Surgery  
(Europe) GmbH**

Hummelsbütteler Steindamm 71  
22851 Norderstedt  
GERMANY

### Product Category(ies):

**Surgical Devices for Instrument Access,  
Cutting, Stapling and Suturing;  
Ultrasonic Surgical Devices and Accessories;  
Electrosurgical Devices and Accessories;  
Instruments for Minimally Invasive Endoscopic Procedures  
(Surgical or through natural body orifices),  
except Class I devices  
(non-sterile and/or without measuring function)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

### Report No.:

713043153

### Valid from:

2014-07-01

### Valid until:

2019-06-30

Date, 2014-06-18

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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(Devices in Class IIa, IIb or III)****No. G1 14 06 57666 045****Facility(ies):**

Ethicon Endo-Surgery, Inc.  
3801 University Boulevard SE, Albuquerque, NM 87106, USA

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Colonia Salvarcar 118, 32580 Ciudad Juarez, Chihuahua,  
MEXICO

Ethicon Endo-Surgery S.A. de C.V. Planta II  
Calle Durango No. 2751, Colonia Lote Bravo, 32575 Ciudad  
Juarez, Chihuahua, MEXICO

Ethicon Endo-Surgery, Inc.  
4545 Creek Road, Cincinnati OH 45242, USA

Ethicon Endo-Surgery, LLC  
475 Calle C, 00969 Guaynabo, PUERTO RICO USA