





Product Service

Certificate

No. Q5 057666 0058 Rev. 03

Holder of Certificate: Ethicon Endo-Surgery, LLC

> 475 Calle C 00969 Guaynabo PUERTO RICO USA

Certification Mark:



Design and development, production and distribution of Scope of Certificate: endoscopic and conventional cutters and staplers,

clip appliers, endoscopic access device systems,

endoscopic grasping and cutting devices, ultrasonic surgical devices, electrosurgical devices, suturing device systems and absorbable sterile surgical implants to support the staple

Servicing of ultrasonic surgical and electrosurgical devices

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 057666 0058 Rev. 03

Report No.: 713281446

Valid from: 2023-04-01 Valid until: 2026-03-31

2023-03-30

Christoph Dicks

Head of Certification/Notified Body

Date,





Certificate

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Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Ethicon Endo-Surgery, LLC

475 Calle C, 00969 Guaynabo, PUERTO RICO USA

Design and development, production and distribution of endoscopic and conventional cutters and staplers, clip appliers, endoscopic access device systems, endoscopic grasping and cutting devices, ultrasonic surgical devices, electrosurgical devices, suturing device systems and absorbable sterile surgical implants to support the staple line

Ethicon Endo-Surgery, Inc.

4545 Creek Road, Cincinnati OH 45242, USA

Design and development, production and distribution of endoscopic and conventional cutters and staplers, clip appliers, endoscopic access device systems, endoscopic grasping and cutting devices, ultrasonic surgical devices, electrosurgical devices, suturing device systems and absorbable sterile surgical implants to support the staple line;
Servicing of ultrasonic surgical devices and electrosurgical devices

Ethicon Endo-Surgery S.A. de C.V. Planta II

Calle Durango No. 2751, Colonia Lote Bravo, 32575 Ciudad Juarez, Chihuahua, MEXICO

Production of endoscopic and conventional cutters and staplers, clip appliers, endoscopic access device systems, endoscopic grasping and cutting devices, ultrasonic surgical devices, electrosurgical devices and suturing device systems

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