



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class IIa and Class IIb Devices)

**No. G10 057666 0064 Rev. 07**

### Manufacturer:

**Ethicon Endo-Surgery, LLC**

475 Calle C  
00969 Guaynabo  
PUERTO RICO USA

SRN Manufacturer - US-MF-000013107

### Authorized Representative:

Johnson & Johnson Medical GmbH  
Robert-Koch-Strasse 1, 22851 Norderstedt, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 057666 0064 Rev. 07](http://www.tuvsud.com/ps-cert?q=cert:G10 057666 0064 Rev. 07)

**Report No.:** 713266424

**Preceding Certificate No.:** G10 057666 0064 Rev. 06

**Valid from:** 2024-05-23

**Valid until:** 2026-01-14

**Date of Initial Issuance:** 2021-01-15

**Issue date:** 2024-05-23

Christoph Dicks  
Head of Certification/Notified Body



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**Classification:**

Class IIa

**Device Group:**

H020101 - MECHANICAL SKIN STAPLERS

**Intended Purpose:**

N/A

**Classification:**

Class IIa

**Device Group:**

K010201 - MINIMALLY INVASIVE SURGERY SURGICAL  
 INSTRUMENTS, SINGLE-USE

**Intended Purpose:**

N/A

**Classification:**

Class IIa

**Device Group:**

K010101 - TROCAR, SINGLE-USE

**Intended Purpose:**

N/A

**Classification:**

Class IIa

**Device Group:**

H020201 - LINEAR STAPLERS, OPEN SURGERY

**Intended Purpose:**

N/A

**Classification:**

Class IIa

**Device Group:**

K0104 - VERESS NEEDLES

**Intended Purpose:**

N/A

**Classification:**

Class IIb

**Device Group:**

Z120109 - ELECTROSURGICAL INSTRUMENTS

**Intended Purpose:**

Intended to supply energy to electrosurgical and ultrasonic surgical instruments

**Classification:**

Class IIb

**Device Group:**

K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS,  
 SINGLE-USE

**Intended Purpose:**

Ligation and division of vessels; cut and seal vessels, cut, grasp,  
 and dissect tissue during surgery; can be used on vessels  
 (arteries, veins, pulmonary vasculature, lymphatics)

**Classification:**

Class IIb

**Device Group:**

K020201 - ULTRASONIC SURGERY INSTRUMENTS, SINGLE-  
 USE

**Intended Purpose:**

Indicated for soft tissue incisions when bleeding control and  
 minimal thermal injury are desired



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**Classification:**

Class IIb

**Device Group:**

Z120109 - ELECTROSURGICAL INSTRUMENTS

**Intended Purpose:**

Intended to convert electrical energy from a compatible Generator to mechanical motion for the instrument blades

**Classification:**

Class IIb

**Device Group:**

K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE

**Intended Purpose:**

Intended for facilitating grasping, mobilization, dissection and transection of tissue

**Classification:**

Class IIb

**Device Group:**

K020101 - MONO- AND BIPOLAR SURGICAL INSTRUMENTS, SINGLE-USE

**Intended Purpose:**

Intended for facilitating tissue dissection, coagulation, irrigation and fluid evacuation through a common trocar sleeve

**Classification:**

Class IIb

**Device Group:**

H020203 - SEMICIRCULAR STAPLERS FOR OPEN SURGERY

**Intended Purpose:**

Intended for transection and resection of tissue

**Classification:**

Class IIb

**Device Group:**

H020202 - CIRCULAR STAPLERS FOR OPEN SURGERY

**Intended Purpose:**

Intended for creation of anastomoses

**Classification:**

Class IIb

**Device Group:**

H020302 - CIRCULAR STAPLERS FOR VIDEOSURGERY

**Intended Purpose:**

Intended for creation of anastomoses

**Classification:**

Class IIb

**Device Group:**

H020201 - LINEAR STAPLERS, OPEN SURGERY

**Intended Purpose:**

Intended for transection, resection and/or creation of anastomoses

**Classification:**

Class IIb

**Device Group:**

H020201 - LINEAR STAPLERS, OPEN SURGERY

**Intended Purpose:**

Intended for the approximation of internal tissues

**Classification:**

Class IIb

**Device Group:**

H020301 - LINEAR STAPLERS FOR VIDEOSURGERY

**Intended Purpose:**

Intended for transection, resection and/or creation of anastomoses



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**Classification:**

Class IIb

**Device Group:**

H020401 - SINGLE PATIENT TRANSANAL RECTAL STAPLERS

**Intended Purpose:**

Intended to simultaneously cut and staple hemorrhoidal tissue and redundant mucosa

**The validity of this certificate depends on conditions and/or is limited to the following:** ./.

### Revision History:

Rev.	Dated	Report	Description
00	2021-01-15	713181354	-
01	2022-03-04	713201749	-
02	2022-03-08	713220847	-
03	2022-11-10	713223764 / 713271082	-
04	2024-01-30	713223834	Supplemented: Device(s)/group of device(s) added
05	2024-02-07	713263019	Supplemented: Device(s)/group of device(s) added
06	2024-03-20	713267122 / 713266417	Supplemented: Device(s)/group of device(s) added
07	2024-05-23	713266424	Supplemented: Device(s)/group of device(s) added