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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

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

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

Digitally signed by Vidiborschii Vladimir
Date: 2025.04.26 11:02:28 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Christoph Dicks
Head of Certification/Notified Body

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(Class IIa and Class IIb Devices)

No. G10 057666 0064 Rev. 07

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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(Class IIa and Class IIb Devices)

No. G10 057666 0064 Rev. 07

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

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