EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 719656 R000

Manufacturer: Ethicon, LLC

Address:
475 C Street, Los Frailes Industrial Park
Guaynabo
Puerto Rico
00969
USA

Single Registration Number: US-MF-000013111

EU Authorised Representative: Johnson & Johnson Medical GmbH

Address:
Robert-Koch-Strasse 1
Norderstedt
22851
Germany

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-10-13**

Current Issue Date: **2023-12-08**

Starting Validity Date: **2023-12-08**

Expiry Date: **2028-10-12**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

PDS™ II Suture is indicated for use in general soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur. PDS™ II Suture is not indicated in adult cardiovascular and neurological tissues. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.
Endosuture System made with PDS™ II Suture is intended for use in general soft tissue approximation and/or ligation involving endoscopic suturing when the use of absorbable suture is appropriate. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.
Standard endoscopic procedures should be followed up to the point where Endosuture System made with PDS™ II Suture is used.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
PDS II Suture	PDS II Suture	MDN 1104	Class III, Implantable	0705031a007965T
Endosuture System Made with PDS II Suture	Endosuture System Made with PDS II Suture	MDN 1104	Class III, Implantable	0705031a0211047

Additional Information:

Surgical needle and suture combinations from within the following limits define the device range for PDS™ II (Polydioxanone) Sterile Synthetic, Absorbable Suture

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Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Absorbable
Suture Gauge Size	0.5 – 5.0 (Metric)
Suture Length	20 cm – 240 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (if dyed)	Violet #2
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Accessories to Suture Type	N/A
Needled/Non-Needled	Needled/Non-Needled
Number of Needles per Suture	Single Armed/Double Armed
Needle Material	420 SS, 4310 SS, and ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight/Curve
Needle Color	Silver/Black
Needle Length	6.5 mm – 254 mm
Needle Wire Diameter	0.152 mm – 1.45mm

Product Name (as Indicated on DoC)	Product Code	Product Description
Endosuture System Made with PDS™ II Suture	EA12	PDSII VIO 44IN(110CM) USP2-0(M3) S/A EN-3 ESS
Endosuture System Made with PDS™ II Suture	EA62G	PDSII VIO 44IN(110CM) USP2-0(M3) S/A SHT VB ESS
Endosuture System Made with PDS™ II Suture	EZ11	PDSII VIO 20IN(50CM) USP0(M3.5) NON NDL ESS ENDOLOOP

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2023-10-13	3091935	Issued.
Current	30031088	Amended - Change in the in-process raw material foil pouch used to store the PDS clear raw material suture.

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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