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.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 719610 R000

Manufacturer: Ethicon, LLC

Address:
475 C Street, Los Frailes Industrial Park
Suite 401
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 examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II 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: **2021-10-14**

Current Issue Date: **2023-07-05**

Starting Validity Date: **2023-07-05**

Expiry Date: **2026-10-13**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 719610 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	**Intended purpose**
ETHICON SECURESTRAP™ Family of Products	See MDR 719665
MERSILENE™ Suture	See MDR 719649
MONOCRYL™ Suture	See MDR 719654
VICRYL RAPIDE™ Suture	See MDR 719664
ETHIBOND EXCEL™ Suture	See MDR 719647
VICRYL™ Suture	See MDR 719663
ETHILON™ Suture	See MDR 719648
PROLENE™ Suture	See MDR 719658
PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures	See MDR 719650
Class IIb, Implantable, Well-established technologies	**Intended purpose**
Stainless Steel Suture	Stainless Steel Suture is indicated for use in sternal closure and orthopedic procedures.

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	**Risk Classification**
Suturing Device	Class Ir

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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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
2021-10-14	3091327	Issued
2023-01-13	3736760	Supplemented – Addition of MERSILENE Suture, MONOCRYL Suture, VICRYL RAPIDE Suture, ETHIBOND EXCEL Suture and VICRYL Suture Amended – Addition of Legal Manufacturer Single Registration Number Amended – Administrative correction to Legal Manufacturer and EU Authorised Representative address format
2023-03-08	3814853	Supplemented – Addition of Coated VICRYL Plus Antibacterial Suture
Current	3908217	Supplemented – Addition of ETHILON Suture, PROLENE Suture, PERMA-HAND Braided Silk and Virgin Silk Non-Absorbable Suture, and Stainless Steel Suture.

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Starting Validity Date: **2023-07-05**

Expiry Date: **2026-10-13**

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