EU Technical Documentation Assessment Certificate

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

MDR 753191 R000

Manufacturer: Ethicon, LLC

Address:
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Single Registration Number: US-MF-000013112

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: **2023-07-20**

Current Issue Date: **2023-07-20**

Starting Validity Date: **2023-07-20**

Expiry Date: **2028-07-19**

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EU Technical Documentation Assessment Certificate

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

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Intended Purpose as per the Instructions for Use:
PROLENE™ Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurosurgical procedures.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
PROLENE Suture	PROLENE Suture	MDN 1104	Class III, Implantable	0705031a012584Z

Additional Information:

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.2 – 5.0 (Metric)
Suture Length	7 cm – 150 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Blue
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Accessories to suture type	PTFE Pledgets
Additional Presentations	HEMO-SEAL needle suture combination
Needled/Non-Needled	Needled (also available with CONTROL RELEASE needles)

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Suture Characteristics	Range
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY and Tungsten/Rhenium
Needle Coating	Silicone, EVERPOINT, CERBERUS, MULTIPASS, MULTIPASS + Additional Coating of Silicone (Double-Dip)
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Dimensions (Except EVERPOINT™)	
Needle Length	3.8 mm – 90 mm
Needle Wire Diameter	0.076 mm – 1.448 mm
Needle Dimensions (EVERPOINT™)	
Needle Length	6.5mm – 13 mm
Needle Wire Diameter	0.1524 mm – 0.2667 mm

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

MDR 753191 R000

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
Current	3483391	Issued

First Issue Date: **2023-07-20**

Current Issue Date: **2023-07-20**

Starting Validity Date: **2023-07-20**

Expiry Date: **2028-07-19**

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EU Quality Management System Certificate

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

MDR 753178 R000

Manufacturer: Ethicon, LLC

Address:
Highway 183 Km 8.3
San Lorenzo
Puerto Rico
00754
USA

Single Registration Number: US-MF-000013112

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: **2022-02-23**

Current Issue Date: **2023-07-20**

Starting Validity Date: **2023-07-20**

Expiry Date: **2027-02-22**

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EU Quality Management System Certificate

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

MDR 753178 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
PROLENE™ Mesh and PROLENE™ Soft Mesh	See MDR 753200
MERSILENE™ Suture	See MDR 753185
ETHIBOND EXCEL™ Suture	See MDR 753190
SURGICEL™ Fibrillar and SURGICEL™ SNoW Absorbable Haemostat	See MDR 753179
SURGICEL™ Powder Absorbable Haemostatic Powder	See MDR 753181
PROLENE™ Suture	See MDR 753191
PRONOVA™ Suture	See MDR 753195
PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures	See MDR 753197

Class III	Intended purpose
Temporary Cardiac Pacing Wire	See MDR 753183

Class IIb, Implantable, Well-established technologies	Intended Purpose
Stainless Steel Suture	Stainless Steel Suture is indicated for use in sternal closure and orthopaedic procedures

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

Device(s)	Risk Classification
DERMABOND™ PRINEO™ Skin Closure System	Class IIa
DERMABOND™ and DERMABOND ADVANCED™ Topical Skin Adhesive	Class IIa

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Starting Validity Date: **2023-07-20**

Expiry Date: **2027-02-22**

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EU Quality Management System Certificate

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

MDR 753178 R000

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
2022-02-23	3483343	Issued
2022-07-13	3693408	Supplemented – Addition of PROLENE Meshes. Amended – Addition of three subcontractors for Manufacture of PROLENE Mesh; addition of two subcontractors for ETO Sterilization and Gamma Sterilization of PROLENE Mesh
2023-03-20	3735352	Supplemented – Addition of MERSILENE Suture, ETHIBOND EXCEL Suture, SURGICEL Fibrillar/SNoW Absorbable Haemostat and SURGICEL Powder Absorbable Haemostatic Powder Amended – Administrative updates to previous history entry for Reference Number 3693408 Amended – Correction of classification of Temporary Cardiac Pacing Wire from Class III, Implantable to Class III
Current	3827515	Supplemented – Addition of PROLENE Suture, PRONOVA Suture, PERMA-HAND Braided Silk and Virgin Silk Non-Absorbable Sutures, Stainless Steel Suture, DERMABOND PRINEO Skin Closure System and DERMABOND and DERMABOND ADVANCED Topical Skin Adhesive

First Issue Date: **2022-02-23**

Current Issue Date: **2023-07-20**

Starting Validity Date: **2023-07-20**

Expiry Date: **2027-02-22**

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