EU Technical Documentation Assessment Certificate

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

MDR 753193 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: **2023-09-29**

Current Issue Date: **2023-09-29**

Starting Validity Date: **2023-09-29**

Expiry Date: **2028-09-28**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

ETHILON™ 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**
ETHILON Suture	ETHILON Suture	MDN 1104	Class III, Implantable	0705031a011995A

Additional Information:

Surgical needle and suture combinations from within the following limits define the device range for ETHILON™ Polyamide 6 or 6,6 Sterile Synthetic Non-Absorbable Surgical Suture.

Suture Characteristics	**Range**
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.1 – 4.0 (Metric)
Suture Length	10 cm – 100 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Green
Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Accessories to suture type	N/A
Needled/Non-Needled	Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 4310 SS, 455 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve

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Suture Characteristics	Range
Needle Color	Silver / Black
Needle Length	3.5 mm – 90 mm
Needle Wire Diameter	0.051 mm – 1.270 mm

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MDR 753193 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	3483393	Issued

First Issue Date: **2023-09-29**

Current Issue Date: **2023-09-29**

Starting Validity Date: **2023-09-29**

Expiry Date: **2028-09-28**

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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: **2024-04-17**

Starting Validity Date: **2024-04-17**

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
ETHIBOND EXCEL™ Suture	See MDR 753190
ETHILON™ Suture	See MDR 753193
MERSILENE™ Suture	See MDR 753185
PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures	See MDR 753197
PROLENE™ Mesh and PROLENE™ Soft Mesh	See MDR 753200
PROLENE™ Suture	See MDR 753191
PRONOVA™ Suture	See MDR 753195
SURGICEL™ Fibrillar and SURGICEL™ SNoW Absorbable Haemostat	See MDR 753179
SURGICEL™ Powder Absorbable Haemostatic Powder	See MDR 753181

Class III	Intended purpose
Temporary Cardiac Pacing Wire	See MDR 753183

Class IIb, Implantable, Well-established technologies	Intended Purpose
MERSILENE™ Tape	MERSILENE™ Tape is indicated for circular suture of the cervix.
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™ and DERMABOND ADVANCED™ Topical Skin Adhesive	Class IIa
DERMABOND™ PRINEO™ Skin Closure System	Class IIa
SURGICEL™ Endoscopic Applicator	Class IIa

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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
2023-07-20	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
2023-09-29	30003402	Supplemented – Addition of ETHILON Suture and SURGICEL Endoscopic Applicator
Current	30011573	Supplemented – Addition of MERSILENE Tape Amended – Device listing rearranged in alphabetical order

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

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