

# EU Technical Documentation Assessment Certificate

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

## MDR 753197 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

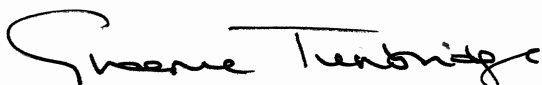
**Address:**

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

## MDR 753197 R000

### Intended Purpose as per the Instructions for Use:

Silk 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
Silk Sterile Non-Absorbable Surgical Suture	Silk Suture	MDN 1104	Class III, Implantable	0705031a011944Y

### Additional Information:

Surgical needle and suture combinations from within the following limits define the device range for PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Suture.

Suture Characteristics	Range
Suture Material (Absorbable/Non-Absorbable)	Non-Absorbable
Suture Gauge Size	0.4 – 5.0 (Metric)
Suture Length	20 cm – 366 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Black / Blue

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Suture Characteristics	Range
Coated/Uncoated	Coated / Uncoated
Multifilament/Monofilament	Multifilament
Accessories to suture type	Retention Tube
Needled/Non-Needled	Needled (also available with CONTROL RELEASE™ needles) / Non-Needled
Number of Needles per Suture	Single Armed / Double Armed
Needle Material	420 SS, 455 SS, 4310 SS, ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Straight / Curve
Needle Color	Silver / Black
Needle Length	5 mm – 90 mm
Needle Wire Diameter	0.15 mm – 1.27 mm

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**MDR 753197 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	3483397	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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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 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

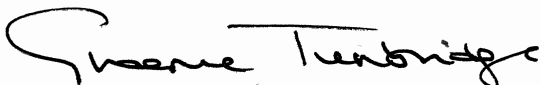
**Address:**

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**

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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

PROLENE™ Mesh and PROLENE™ Soft Mesh

MERSILENE™ Suture

ETHIBOND EXCEL™ Suture

SURGICEL™ Fibrillar and SURGICEL™ SNoW Absorbable Haemostat

SURGICEL™ Powder Absorbable Haemostatic Powder

PROLENE™ Suture

PRONOVA™ Suture

PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures

#### Intended purpose

See MDR 753200

See MDR 753185

See MDR 753190

See MDR 753179

See MDR 753181

See MDR 753191

See MDR 753195

See MDR 753197

#### Class III

Temporary Cardiac Pacing Wire

#### Intended purpose

See MDR 753183

#### Class IIb, Implantable, Well-established technologies

Stainless Steel Suture

#### Intended Purpose

Stainless Steel Suture is indicated for use in sternal closure and orthopaedic procedures

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

#### Device(s)

DERMABOND™ PRINEO™ Skin Closure System

DERMABOND™ and DERMABOND ADVANCED™ Topical Skin Adhesive

#### Risk Classification

Class IIa

Class IIa

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# EU Quality Management System Certificate

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## 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](mailto: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**

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

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