By Royal Charter

EU Technical Documentation Assessment Certificate

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

MDR 730060 R000

Manufacturer: Johnson & Johnson International

Address:
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

Single Registration Number: BE-MF-000008018

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: **2023-07-26**

Current Issue Date: **2023-07-26**

Starting Validity Date: **2023-07-26**

Expiry Date: **2028-07-25**

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Device Schedule:

Intended Purpose as per the Instructions for Use:
MONOCRYL™ Plus Sutures are indicated for use in general soft tissue approximation and/or ligation, but not for use in cardiovascular or neurological tissues or ophthalmic surgery.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
MONOCRYL Plus Antibacterial poliglecaprone 25 monofilament absorbable suture	MONOCRYL Plus Antibacterial Suture	MDN 1104	Class III, implantable	0705031a0071857

Additional information:
Surgical needle and suture combinations from within the following limits define the device range for MONOCRYL™ Plus Antibacterial poliglecaprone 25 monofilament absorbable suture.

Suture Characteristic	**Range**
Suture Material	Absorbable
Suture Gauge Size	0.7 – 4.0 (Metric)
Suture Length	45 – 90 cm
Suture Dyed/Undyed	Dyed / Undyed
Suture Color (If dyed)	Violet # 2
Suture Coated/Uncoated	Uncoated
Multifilament/Monofilament	Monofilament
Contains Antimicrobials (Yes/No)	Yes
Triclosan Maximum Levels	≤ 2360 µg/m
Accessories to suture type	N/A
Suture Needled/Non-Needled	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

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Suture Characteristic	Range
Needle Color	Silver / Black
Needle Length	10 – 60.3 mm
Needle Wire Diameter	0.25 – 1.3mm

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MDR 730060 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	3219955	Issued.

First Issue Date: **2023-07-26**

Current Issue Date: **2023-07-26**

Starting Validity Date: **2023-07-26**

Expiry Date: **2028-07-25**

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EU Quality Management System Certificate

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

MDR 729796 R000

Manufacturer: Johnson & Johnson International

Address:
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

Single Registration Number: BE-MF-000008018

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: **2022-04-11**

Current Issue Date: **2023-07-26**

Starting Validity Date: **2023-07-26**

Expiry Date: **2027-04-10**

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EU Quality Management System Certificate

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

MDR 729796 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
VICRYL™ Suture	See MDR 730029
MERSILENE™ Suture	See MDR 730030
MONOCRYL™ Suture	See MDR 730032
Coated VICRYL™ Plus Antibacterial Suture	See MDR 730033
PROCEED™ Ventral Patch	See MDR 730040
VICRYL RAPIDE™ Suture	See MDR 730044
ETHIBOND EXCEL™ Suture	See MDR 730045
ULTRAPRO™ Mesh and ULTRAPRO ADVANCED™ Mesh	See MDR 730047
ULTRAPRO™ Plug	See MDR 730048
ULTRAPRO™ Hernia System	See MDR 730049
PERMA-HAND™ Braided Silk Non-Absorbable Suture	See MDR 730051
PDS™ Cord	See MDR 730058
LAPRA-TY™ II Clips	See MDR 730059
PROCEED™ Surgical Mesh	See MDR 730258
PDS™ II Suture	See MDR 730038
PDS™ Plus Antibacterial Suture	See MDR 730053
MONOCRYL™ Plus Antibacterial Suture	See MDR 730060

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

Device(s)	Risk Classification
Clipping Devices	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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EU Quality Management System Certificate

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

MDR 729796 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
2022-04-11	3217916	Issued
2022-06-20	3675349	Supplemented – Addition of PROCEED Surgical Mesh
2022-07-07	3694404	Supplemented – Addition of ULTRAPRO Hernia System
2022-12-20	3735261	Supplemented – Addition of MERSILENE Suture, MONOCRYL Suture, VICRYL RAPIDE Suture, ETHIBOND EXCEL Suture and VICRYL Suture
2023-03-08	3814851	Supplemented – Addition of Coated VICRYL Plus Antibacterial Suture
2023-05-30	3846444	Supplemented – Addition of PDS™ Cord, PERMA-HAND™ Braided Silk Non-Absorbable Suture, and ULTRAPRO™ Mesh and ULTRAPRO ADVANCED™ Mesh
Current	3915286	Supplemented – addition of PDS™ II Suture, PDS™ Plus Antibacterial Suture, and MONOCRYL™ Plus Antibacterial Suture.

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