EU Technical Documentation Assessment Certificate

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

MDR 730029 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: **2022-12-16**

Current Issue Date: **2022-12-16**

Starting Validity Date: **2022-12-16**

Expiry Date: **2027-12-15**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

MDR 730029 R000

Device Schedule:

Intended Purpose as per the Instructions for Use:

VICRYL™ Sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, but not for use in cardiovascular and neurological tissues.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
VICRYL Suture	VICRYL Suture	MDN 1104	Class III, Implantable	0705031a0113046

Additional Information:

Surgical needle and suture combinations from within the following limits define the device range for VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture

Suture Characteristics	**Range**
Surgical Suture Material (Absorbable/Non-Absorbable)	Absorbable
Surgical Suture Gauge Size	0.2 – 8.0 (Metric)
Surgical Suture Length	5 cm – 2.5 m
Surgical Suture Dyed/Undyed	Dyed/Undyed
Surgical Suture Color (If dyed)	Violet
Coated/Uncoated	Coated (Copolymer of glycolide and L-lactide, calcium stearate)/Uncoated
Multifilament/Monofilament	Multifilament/Monofilament
Accessories to suture type	N/A
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, and ETHALLOY
Needle Coating	Silicone, CERBERUS, MULTIPASS
Needle Shape	Curve/Straight
Needle Color	Silver/Black
Needle Length	3.5 mm – 110 mm
Needle Wire Diameter	0.015 mm – 1.60 mm

First Issue Date: **2022-12-16**

Current Issue Date: **2022-12-16**

Starting Validity Date: **2022-12-16**

Expiry Date: **2027-12-15**

...making excellence a habit.™

EU Technical Documentation Assessment Certificate

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

MDR 730029 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	3219877	Issued

First Issue Date: **2022-12-16**

Current Issue Date: **2022-12-16**

Starting Validity Date: **2022-12-16**

Expiry Date: **2027-12-15**

...making excellence a habit.™

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.