

EU Quality Management System Certificate

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

MDR 729796 R000

Manufacturer: Johnson & Johnson International

Address:

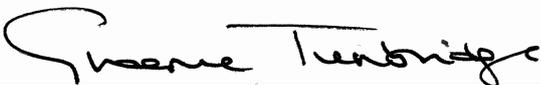
c/o European Logistics Centre
Leonardo Da Vincilaan 15
BE-1831 Diegem
Belgium

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: **2024-03-21**

Starting Validity Date: **2024-03-21**

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

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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 |
| ETHICON PHYSIOMESH™ Open Flexible Composite Mesh | See MDR 730035 |
| VICRYL™ Mesh | See MDR 730031 |

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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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 |
| 2023-07-26 | 3915286 | Supplemented – Addition of PDS™ II Suture, PDS™ Plus Antibacterial Suture, and MONOCRYL™ Plus Antibacterial Suture. |
| 2023-11-10 | 30008523 | Supplemented – Addition of ETHICON PHYSIOMESH™ Open Flexible Composite Mesh |
| Current | 30119028 | Supplemented – Addition of VICRYL™ Mesh |

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