By Royal Charter

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: **2023-03-08**

Starting Validity Date: **2023-03-08**

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

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Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
PROCEED™ Ventral Patch	See MDR 730040
ULTRAPRO™ Plug	See MDR 730048
LAPRA-TY™ II Clips	See MDR 730059
PROCEED™ Surgical Mesh	See MDR 730258
ULTRAPRO™ Hernia System	See MDR 730049
MERSILENE™ Suture	See MDR 730030
MONOCRYL™ Suture	See MDR 730032
VICRYL RAPIDE™ Suture	See MDR 730044
ETHIBOND EXCEL™ Suture	See MDR 730045
VICRYL™ Suture	See MDR 730029
Coated VICRYL™ Plus Antibacterial Suture	See MDR 730033

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
Current	3814851	Supplemented – Addition of Coated VICRYL Plus Antibacterial Suture

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