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

08 June 2023

Notified Body Confirmation Letter

Reference: EU2023-607/640177

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

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

SRN Number (if available): BE-MF-000008018

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR

application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Lizzy Szott

Digitally signed by Lizzy Szott
Date: 2023.06.08 19:52:21 -04'00'

Lizzy Szott, PhD

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
LAPRA-TY™ II Clips/ 0705031a000083Z	Class III	N/A	CE 589698, NB 2797 CE 511911, NB 2797
ULTRAPRO™ Hernia System/ 0705031a0000943	Class III	N/A	CE 589698, NB 2797 CE 505757, NB 2797
VICRYL™ (Polyglactin 910) Mesh/ 0705031a006835D	Class III	N/A	CE 589698, NB 2797 CE 509893, NB 2797
MONOCRYL™ (Poliglecaprone 25) Sutures/ 0705031a0083256	Class III	N/A	CE 589698, NB 2797 CE 01305, NB 2797
PDS™ Plus Antibacterial (polydioxanone) Sterile Synthetic Absorbable Surgical Suture/ 0705031a0080859	Class III	N/A	CE 589698, NB 2797 CE 536533, NB 2797
MONOCRYL™ Plus Antibacterial Poliglecaprone-25 (Monofilament), Sterile Synthetic Absorbable Surgical Suture/ 0705031a0071857	Class III	N/A	CE 589698, NB 2797 CE 518537, NB 2797
Coated VICRYL™ PLUS Antibacterial (Polyglactin 910) Sterile Synthetic Absorbable Suture/ 0705031a007925K	Class III	N/A	CE 589698, NB 2797 CE 73804, NB 2797
ETHIBOND EXCEL™ Polybutilate Coated Polyester Sterile Synthetic Non-Absorbable Surgical Suture/ 0705031a007064Y	Class III	N/A	CE 589698, NB 2797 CE 00819, NB 2797
PDS™ Plate/ 0705031a007945P	Class III	N/A	CE 589698, NB 2797 CE 511913, NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
PDS™ Cord/ 0705031a0071959	Class III	N/A	CE 589698, NB 2797 CE 508562, NB 2797
VICRYL™ (Polyglactin 910) Sterile Synthetic Absorbable Surgical Suture/ 0705031a0113046	Class III	N/A	CE 589698, NB 2797 CE 00585, NB 2797
PDS™ II (Polydioxanone) Sterile Synthetic, Absorbable Surgical Suture/ 0705031a007975V	Class III	N/A	CE 589698, NB 2797 CE 00414, NB 2797
PERMA-HAND™ Braided Silk and Virgin Silk Non-Absorbable Sutures/ 0705031a0119552	Class III	N/A	CE 589698, NB 2797 CE 01722, NB 2797
VICRYL RAPIDE™ (Polyglactin 910) Synthetic Absorbable Suture/ 0705031a012094L	Class III	N/A	CE 589698, NB 2797 CE 00584, NB 2797
MERSILENE™ Polyester Sterile Synthetic Non-Absorbable Surgical Suture/ 0705031a014514V	Class III	N/A	CE 589698, NB 2797 CE 01130, NB 2797
ETHICON PHYSIOMESH™ Open Flexible Composite Mesh/ 0705031a020164E	Class III	N/A	CE 589698, NB 2797 CE 565501, NB 2797
ULTRAPRO™ Mesh and ULTRAPRO ADVANCED™ Mesh/ 0705031a014524X	Class III	N/A	CE 589698, NB 2797
ARTISYN™ Y-Shaped Mesh/ 0705031a0202249	Class III	N/A	CE 589698, NB 2797
PROCEED™ Surgical Mesh/ 0705031a011534J	Class III	N/A	CE 589698, NB 2797 CE 699129, NB 2797
PROCEED™ Ventral Patch/ 0705031a011514E	Class III	N/A	CE 589698, NB 2797 CE 543381, NB 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ULTRAPRO™ Plug/ 0705031a011524G	Class III	N/A	CE 589698, NB 2797 CE 515809, NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
LAPRA-TY™ II Clip Applier/ 0705031a000023M	Class I device that qualifies as a re-usable surgical instrument	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2023/06/08	Initial issue