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Smith and Nephew Medical Limited
101 Hessle Road
Hull
HU3 2BN
United Kingdom

14 May 2024

Notified Body Confirmation Letter

Reference: EU2023-607/856460

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:

Smith and Nephew Medical Limited
101 Hessle Road
Hull
HU3 2BN
United Kingdom
SRN Number: GB-MF-000017580

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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
ACTICOAT Flex 3 **Basic UDI-DI: 5000223SN000154RG**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 547893 Expiry date: 26/05/2024 NB#: 2797
ACTICOAT Flex 7 **Basic UDI-DI: 5000223SN000153RE**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 544419 Expiry date: 26/05/2024 NB#: 2797
ACTICOAT / ACTICOAT 3 **Basic UDI-DI: 5000223SN000145RF**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 90692 Expiry date: 26/05/2024 NB#: 2797
ACTICOAT 7 **Basic UDI-DI: 500223SN000146RH**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 90692 Expiry date: 26/05/2024 NB#: 2797
Iodosorb Powder **Basic UDI-DI: 500223SN000147RK**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 511078 Expiry date: 26/05/2024 NB#: 2797
Iodosorb Dressing **Basic UDI-DI: 500223SN000149RP**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 511078 Expiry date: 26/05/2024 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
Iodosorb Ointment **Basic UDI-DI: 500223SN000148RM**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 511078 Expiry date: 26/05/2024 NB#: 2797
Bactigras **Basic UDI-DI: 5000223SN000144RD**	Class III	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797 MDD Certificate #2: CE 01105 Expiry date: 26/05/2024 NB#: 2797
Allevyn Non-adhesive **Basic UDI-DI: 5000223SN000128RF**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Allevyn Gentle **Basic UDI-DI: 5000223SN000170RE**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Allevyn Adhesive **Basic UDI-DI: 5000223SN000127RD**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS AB Abdominal Kit **Basic UDI-DI: 5000223SN000137RG**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS-F Foam Dressing kit with Soft Port and Transparent Film **Basic UDI-DI: 5000223SN000172RJ**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS Gauze Dressing kits **RENASYS Drain Dressing kits** **Basic UDI-DI: 5000223SN000161RD**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
RENASYS Drain Accessory kits	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024

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
Basic UDI-DI: 5000223SN000162RF			NB#: 2797
RENASYS TOUCH Non-Connect **Basic UDI-DI: 5000223SN000138RJ**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
PROFORE Multi-Layer Bandage System **Basic UDI-DI: 5000223SN000131R4**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Intrasite Conformable **Basic UDI-DI: 5000223SN000129RH**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
PICO 7 / PICO 7Y / PICO 14 **Basic UDI-DI: 5000223SN000135RC**	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Versajet III console **Basic UDI-DI: 5000223SN000176RS**	Class IIb excluding Class IIb implantable non-WET	Versajet II console	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Versajet III foot switch **Basic UDI-DI: 5000223SN000177RU**	Class IIb excluding Class IIb implantable non-WET	Versajet II foot switch	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Versajet III handpiece **Basic UDI-DI: 5000223SN000175RQ**	Class IIa	Versajet II handpiece	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Solosite **Basic UDI-DI: 5000223SN000125R9**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Cuticerin **Jelonet Plus** **Basic UDI-DI: 5000223SN000118RC**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Proshield Plus **Basic UDI-DI: 5000223SN000159RS**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 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
Proshield Foam & Spray **Basic UDI-DI: 5000223SN000160RB**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Opsite Spray **Basic UDI-DI: 5000223SN000111QW**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
SECURA No-Sting Barrier Film **Basic UDI-DI: 5000223SN000124R7**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 NB#: 2797
Skin Prep **Basic UDI-DI: 5000223SN000168RT**	Class IIa	N/A	MDD Certificate #1: CE 00356 Expiry date: 26/05/2024 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/05/14	Initial issue