3M Company,

2510 Conway Avenue E,

St Paul

MN 55144

USA

29th March 2024

Notified Body Confirmation Letter

Reference: EU2023-607/805515

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:

3M Company,

2510 Conway Avenue E,

St Paul

MN 55144

USA

SRN Number (if available): US-MF-000014086

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

NB 2797

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
3M™ Cavilon™ Advanced Skin Protectant	Class IIa	N/A	CE 00493; NB # 2797
3M™ Curos™ Disinfecting Caps, Tips, and Cap Strips	Class IIa	N/A	CE 00493; NB # 2797
3M™ Cavilon™ No Sting Barrier Film (Wipes/wands)	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Bair Hugger™ Warming Blankets (Sterile)	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Coban™ Self-Adherent Wrap (Sterile)	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Steri-Strip™ Closures	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Medipore™ +Pad Cloth Adhesive Wound Dressing	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Steri-Drape™ Surgical Drape and Accessories	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Skin Stapler Remover	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Nexcare™ Bandages	Class I device placed on the market in sterile condition	N/A	CE 00493; NB # 2797
3M™ Tegaderm™ CHG I.V. Securement Dressing	Class III	N/A	CE 02242; NB# 2797 CE 525600; NB# 2797
3M™ Tegaderm™ CHG I.V. Port Dressing	Class III	N/A	CE 02242; NB# 2797 CE 525600; NB# 2797
3M™ Tegaderm™ Antimicrobial Transparent Dressing	Class III	N/A	CE 02242; NB# 2797 CE 698003; NB# 2797
3M™ Tegaderm™ Antimicrobial I.V.	Class III	N/A	CE 02242; NB# 2797 CE 698003; NB# 2797

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
Advanced Securement Dressing			
3M™ Ioban™ 2 Antimicrobial Incise Drapes	Class III	N/A	CE 02242; NB# 2797 CE 89073; NB# 2797
3M™ Steri-Drape™ Ioban™ 2 Specialty Drapes	Class III	N/A	CE 02242; NB# 2797 CE 89073; NB# 2797
3M™ Electrosurgical Plates	Class IIb excluding Class IIb implantable non-WET	N/A	CE 02242; NB# 2797
3M™ Steri-Vac™ Sterilizers/Aerators and Steri-Gas™ cartridges	Class IIb excluding Class IIb implantable non-WET	N/A	CE 02242; NB# 2797
3M™ Ranger™ Pressure Infusor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 02242; NB# 2797
3M™ Ranger™ Blood/Fluid Warming Unit	Class IIb excluding Class IIb implantable non-WET	N/A	CE 02242; NB# 2797
3M™ Bair Hugger™ Warming Unit and Sensor	Class IIb excluding Class IIb implantable non-WET	N/A	CE 02242; NB# 2797
3M™ Bair Hugger™ Temperature Monitoring System, Sensor and Control Unit	Class IIa	N/A	CE 02242; NB# 2797
3M™ Ranger™ Blood/Fluid Warming Disposable Sets	Class IIa	N/A	CE 02242; NB# 2797
3M™ Ranger™ Irrigation Fluid Warming Unit	Class IIb excluding Class IIb implantable non-WET	N/A	CE 02242; NB# 2797
3M™ Ranger™ Irrigation Fluid Warming System Disposable Sets	Class IIa	N/A	CE 02242; NB# 2797
3M™ Steri-Drape™ Isolation Bag and Wound Edge Protector Drape	Class IIa	N/A	CE 00493; NB # 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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
Device 1		N/A or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 2		'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 3		'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives
Device 4		'N/A' or Identification of the corresponding device under MDD/AIMDD	Certificate #1; NB# Certificate #2; NB # or N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2024/03/11	Initial issue
2024/03/28	Addition of the devices - 3M™ Ranger™ Irrigation Fluid Warming Unit, 3M™ Ranger™ Irrigation Fluid Warming System Disposable Sets, 3M™ Steri-Drape™ Isolation Bag and Wound Edge Protector Drape.