Geuder AG
Hertzstraße 4
Heidelberg
69126
Germany

April 26th, 2024

Notified Body Confirmation Letter

Reference: EU2023-607/821502

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:

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SRN Number: DE-MF-000008044

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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
Single-Use Light Conductors / Fiber Optics, sterile, incl. Uno Colorline	Class IIa	N/A	CE 575415; NB# 2797
Single-Use Accessory Kits with Ultrasonic Tips, sterile	Class IIa	N/A	CE 575415; NB# 2797
Ultrasonic tips, reusable	Class IIa	N/A	CE 575415; NB# 2797
Single-Use Vitrectomy Instruments Uno Colorline, sterile	Class IIa	N/A	CE 575415; NB# 2797
Single-Use DMEK Cartridge, sterile	Class IIa	N/A	CE 575415; NB# 2797
Single-Use-DMEK-Transportation Cartridge, RAPID	Class IIa	N/A	CE 575415; NB# 2797
Single-Use Adapters, sterile	Class I device placed on the market in sterile condition	N/A	CE 575415; NB# 2797
Single-Use Trocar Systems Uno Colorline, sterile	Class IIa	N/A	CE 575415; NB# 2797
Single-Use Ophthalmic Cannula	Class IIa	N/A	CE 575415; NB# 2797 CE 575413; NB# 2797
Injection-/Infusion Tubing	Class IIa	N/A	CE 575415; NB# 2797
Single-Use Tubing Sets, sterile	Class IIa	N/A	CE 575415; NB# 2797 CE 575413; NB# 2797
Tubing Sets, reusable	Class IIa	N/A	CE 575415; NB# 2797

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Cassettes	Class IIa	N/A	CE 575415; NB# 2797
I/A Instruments, sterile	Class I device that qualifies as a re-usable surgical instrument	N/A	CE 575415; NB# 2797 CE 575413; NB# 2797
	Class I device placed on the market in sterile condition		
Single-Use Vitrectors, sterile, Uno Colorline	Class IIa	N/A	CE 575415; NB# 2797
OcuLED Single-use LED Lightsource, sterile	Class IIa	N/A	CE 575415; NB# 2797
Single-use Endo-probes Uno Colorline, sterile	Class IIa	N/A	CE 575413; NB# 2797
Single-use Knives, sterile	Class IIa	N/A	CE 575413; NB# 2797
Single-use Trephines	Class IIa	N/A	CE 575413; NB# 2797
Single-Use Silicone Implants for Retinal Detachment	Class IIb implantable non-WET	N/A	CE 575415; NB# 2797
Megatron S4 and Megatron S4 HPS surgical systems (incl. G-30543 foot switch)	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711663 NB# 2797
Endotron 532 nm surgical system (incl. G-61101 foot switch)	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711664 NB# 2797
Diathermy Instruments	Class IIb excluding Class IIb implantable non-WET	N/A	CE 711665 NB# 2797
Ultrasonic Handpieces	Class IIb excluding Class IIb implantable non-WET	N/A	CE 575415; NB# 2797
Bonn Injection Set, sterile	Class IIa	N/A	CE 575413; NB# 2797
Measuring Instruments	Class I device with a measuring function	N/A	CE 575413; NB# 2797
	Class I device that qualifies as a re-usable surgical instrument		

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Diamond Knifes	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
Injectors	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
Clamps	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
Curettes and Spoons	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
Lances and Knifes	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
Manipulators	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
Forceps	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
Retractors	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
Scissors	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
Probes	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
Punches	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

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
Trephines	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
Irrigation and Aspiration Instruments	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
Fixation Rings	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
Specula	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
Localizers	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
Markers	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
Needle Holders	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
Razor Blade Holders	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
Cleaning Adapters	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives

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)t	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
2024/04/16	Initial issue