

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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|---|---|--|--|
| 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 |