Bionika Medline Kft.
3516 Miskolc, Tégla
utca 29. Hungary

13/12/2024

Confirmation Letter Reference: CLNB1639 - HU/ BUD/3817

To whom it may concern,

Confirmation of receipt 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, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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

Bionika Medline Kft.
3516 Miskolc, Tégla
utca 29. Hungary
SRN Number (if available): HU-MF-000004631

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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;
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 the Notified Body SGS Belgium NV NB1639,
pp [Jérôme JADOT]

Signé par :
Jérôme JADOT
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Global Medical Device Certification Manager
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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	**MDR Device classification**	**MDD Device name**	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
Dental Implant Systems - Dental implants, sterile Mini System, 4 variants B-UDI: 599322081TM Dental implants, sterile One-stage System, 9 variants B-UDI: 599322080TK Dental implants, sterile two-stage Bionika and Uniform (compatible) system, 67 variants B-UDI: 599322083TR	Class IIb	Dental Implant Systems	N/A	5-856-200-1810 CE 1011
Accessories: Prosthetic Accessory System, non-sterile, 137 variants B-UDI: 599322082TP	Class IIb	Dental Abutments/ Prosthetics	N/A	5-856-200-1810 CE 1011
Re-usable dental surgery instruments with active connection, 1707 variants B-UDI: 599322060TD	Class IIa non-sterile	Bone Surgery Instrument System	N/A	5-856-200-1810 CE 1011

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**

Justification	No such devices for which SGS is not responsible for MDD SUR

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
13/12/2024	**Version 1**	**Initial issue**