Fresenius Kabi AG
Else-Kröner-Str. 1
Bad Homburg v.d.H
61352
Germany
14 November 2023

Notified Body Confirmation Letter
Reference: EU2023-607/727167

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:

Fresenius Kabi AG
Else-Kröner-Str. 1
Bad Homburg v.d.H
61352
Germany
DE-MF-000009273

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

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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 (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	NA	N/A	NA

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
Ringer Solution	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Sodium Chloride 0.9%	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Ringer lactate solution	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Purisole SM diluted	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Glycine 1.5%	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Sterile water	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Solutio R plus	Class IIb excluding Class IIb implantable non-WET	N/A	G1 047402 0083 Rev. 00 NB TÜV SÜD 0123
Lavasorb	Class III	N/A	G7 047402 0087 Rev. 00 NB TÜV SÜD 0123
Freka-Clyss	Class III	N/A	N/A - Device did not require a Notified Body certificate under Directives
Sodium Bicarbonate 1.4%	Class IIa	N/A	N/A - Device did not require a Notified Body certificate under Directives

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Confirmation Letter Revision History

Date	Action
2023/11/16	Initial issue

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