RB Medical Engineering Ltd
Unit 2 Alton Road Industrial Estate
Ross-on-Wye
Herefordshire
HR9 5NS
UK

28/05/2024

Confirmation Letter Reference: CLNB1639 – GB/PC/240492

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:

RB Medical Engineering Ltd
Unit 2 Alton Road Industrial Estate
Ross-on-Wye
Herefordshire
HR9 5NS
UK
SRN: GB-MF-000033667

Authorised Representative:

RB Medical BV
Brouwer 1 (5521 DK)
Eersel
The Netherlands
SRN: NL-AR-00000116

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.

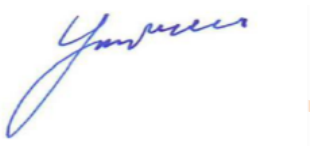
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- 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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 [Haldun OGUZ]

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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** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
Sterile and Non Sterile Suction Irrigation Sets 50564642SUCIRRRD	Class IIa	Sterile & Non Sterile Suction Irrigation Sets	N/A	GB20/965396; NB1639
Single Use Forceps 50564642FORVR	Class IIa	Sterile Single Use Forceps	N/A	GB20/965396; NB1639
Sterile Single Use scissors 50564642SCICUTTSK	Class IIa	Sterile Surgical Scissors & Cutting Instruments,	N/A	GB20/965396; NB1639
Sterile Single Use Retractors 50564642RETRQJ	Class IIa	Sterile Single Use Retractors	N/A	GB20/965396; NB1639
Sterile Single Use Suction Tubes 50564642SUCTRS	Class IIa	Sterile Single Use Suction Tubes	N/A	GB20/965396; NB1639
Sterile and Non Sterile Cautery burners 50564642CAUBURF5	Class IIb	Cautery Burners	N/A	GB20/965396; NB1639
Sterile and Non Sterile TUR electrodes 50564642TURYH	Class IIb	TUR electrodes	N/A	GB20/965396; NB1639
Sterile Single use diathermy electrodes 50564642DIATHG6	Class IIb	Diathermy Electrodes,	N/A	GB20/965396; NB1639
Sterile Single use bipolar forceps 50564642BIPFORGF	Class IIb	Biopolar Forceps	N/A	GB20/965396; NB1639
Battery Operated Cautery Set 50564642JC150AB	Class IIb	Battery Powered	N/A	GB20/965396; NB1639

Device name or Basic UDI-DI	**MDR Device classification** (as proposed by the manufacturer and verified at the pre-application stage)	**MDD Device name** (please indicate if correlation with MDR denomination is not obvious)	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
		Cautery Set JC150,		
Light Duty Cautery Sets, sets include cautery unit, handle and burners. 50564642JC620AT	Class IIb	Light Duty Cautery Set JC620	N/A	GB20/965396; NB1639
Light Duty Cautery Handles – JA113, JA124, JA123, JA124, JA142, JA143 50564642LDCHLU	Class IIb	Cautery Handles	N/A	GB20/965396; NB1639

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**
N/A	N/A	N/A all device SUR will be performed by SGS	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
28/05/2024	Version 1	Initial issue