Rocialle Healthcare Limited
Ty Mynydd
Cwm Cynon Business Park (North)
Mountain Ash
Rhondda Cynon Taff
CF45 4ER
UK

13/12/2023

Confirmation Letter Reference: CLNB1639 GBPC 228898

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement 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:

Rocialle Healthcare Limited
Ty Mynydd
Cwm Cynon Business Park (North)
Mountain Ash
Rhondda Cynon Taff
CF45 4ER
UK

Eu representative:
Advena Limited
Tower Business Centre, 2nd Flr,
Tower Street, Swatar,
BKR 4013, Malta
SRN: MT-AR-000000234

The devices covered by the formal application and the written agreement mentioned above are shown at the end of this letter.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive

93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15 March 2023, this letter also confirms that:

- the manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry;
- the certificates expired after 26 May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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:

- 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 the Notified Body SGS Belgium NV 1639,

Ian How
PP
Virginie SILORET
Global Medical Device Certification Manager
Email: Virginie.siloret@sgs.com
Phone : +41 22 739 98 58

Devices covered by this letter:

Device name / 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
- Sterile and non-sterile single-use surgical instruments: scissors, forceps, retractors, needle holders and curettes used during surgical procedures 5050918TF01SUSINZ	Class IIa	N/A	GB19/964719; NB1639
- Annex V Sterility aspects only - Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. -Sterile single use non-surgical instruments for use during medical procedures. UDI: 5050918TF05SUNSI3M -Assembly packing and sterilisation of surgical and non-surgical instruments and procedure packs in accordance with the requirements of Article 12. UDI: N/A Class: N/A	Is	N/A	GB19/964719; NB1639

Confirmation Letter Revision History

Date	**NB internal reference traceable to each version of the letter**	**Action**
2023/13/12	Version 1	Initial issue