SURGIKARE
Toor Abad,
Daska Road
Sialkot - Pakistan

05-10-2023

Confirmation Letter Reference: CLNB1639 - PK/LHR/221615

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

Legal Manufacturer:
SURGIKARE
Toor Abad, Daska Road
Sialkot - Pakistan

EU Representative:
OBELIS S.A
Bd. General Wahis, 53,
1030 Brussels, Belgium
SRN Number: BE-AR-000000106

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

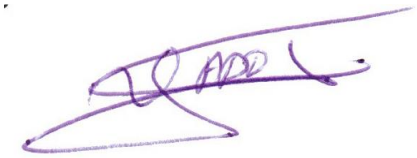
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry; 29 June, 2023
- 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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 1639,



pp [Jérôme JADOT]

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	**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 & Non-Sterile Single Use Bipolar Forceps with & without Cables Basic UDI-DI: (050563825SUBIF210QB)	Sterile & Non-Sterile Single Use Electrosurgical Bipolar Forceps with & without Cables (Class IIb)	N/A	Annex II Certificate #PK19/818842594 NB1639
Sterile & Non-Sterile Single Use Monopolar Electrodes Basic UDI-DI: (050563825SUELT215VX)	Sterile & Non-Sterile Single Use Monopolar Electrodes with & without Handpiece (Class IIb)	N/A	Annex II Certificate #PK19/818842594 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Forceps Basic UDI-DI: (050563825SUFRP110X3)	Sterile & Non-sterile single use Forceps (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Scissors Basic UDI-DI: (050563825SUSCR100XJ)	Sterile & non-Sterile single use Surgical Scissors (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Retractors Basic UDI-DI: (050563825SURET115YN)	Sterile & Non sterile single use Surgical Retractors (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Tweezers Basic UDI-DI: (050563825SUTWZ1058Y)	Sterile & Non sterile single use Tweezers (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639

Device name / Basic UDI-DI	**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 & Non-Sterile Single-Use Surgical Instruments: Curettes Basic UDI-DI: (050563825SUCRT135X8)	Sterile & Non sterile single use Curettes (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Cannulae, Suction Tubes Basic UDI-DI: (050563825SUSCT160YJ)	Sterile & Non sterile single use Suction Tubes & Cannulas (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Needle Holders Basic UDI-DI: (050563825SUNDH130TX)	Sterile & non sterile single use Needle Holders (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Scalpel Handle without blade Basic UDI-DI: (050563825SUSPH1802N)	Sterile & Non sterile single use Scalpel Handles with & without blades (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile & Non-Sterile Single-Use Surgical Instruments: Probes Basic UDI-DI: (050563825SUPRB120Y6)	Sterile & Non-Sterile single use Probes/Dilators (Class IIa)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile Single-Use devices: dental scalars Basic UDI-DI: (050563825SUDIL170SU)	Sterile single use Dental Scalars (Class Is)	N/A	Annex V Certificate #PK19/818842593 NB1639
Sterile Single-Use devices: dental syringes without needle Basic UDI-DI: (050563825SUDTS190YC)	Sterile single use Dental Syringes (Class Is)	N/A	Annex V Certificate #PK19/818842593 NB1639

Device name / Basic UDI-DI	**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 Single-Use devices: vaginal speculae Basic UDI-DI: (050563825SUSPL15039)	Sterile single use Vaginal Speculums (Class Is)	N/A	Annex V Certificate #PK19/818842593 NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/10/05	Version 1	Initial issue