TATA SURGICAL (PVT) LTD
Mughal Street, Muhammad Pura,
Commissioner Road, Sialkot (51310),
Pakistan

06-09-2024

Confirmation Letter Reference: CLNB1639 - PK/SKT/233287

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

Legal Manufacturer:
TATA SURGICAL (PVT) LTD
Mughal Street, Muhammad Pura,
Commissioner Road, Sialkot (51310),
Pakistan
SRN Number: PK-MF-000013542

EU Authorized Representative:
CMC Medical Devices & Drugs SL
C/ Horacio Lengo N18,
29006 Málaga, Spain
SRN Number: ES-AR-000000293

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.

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607

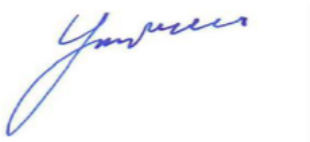
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- 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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SGS NB 1639 - Confirmation letter Regulation (EU) 2023/607

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 & Non-Sterile Single Use General Surgery Scissors (8961103540GS-SCISSORS-XW)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use General Surgery Dissecting & Tissue Forceps (8961103540DISSCT-FCPS-3S)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use General Surgery Hemostatic Forceps (8961103540HEMO-FCPS-WW)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use General Surgery Needle Holders (8961103540N-HOLDERS-V4)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use General Surgery Retractors (8961103540RETRACTORS-LV)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use General Surgery Suction Tubes	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639

SGS NB1639 - Confirmation letter Regulation (EU) 2017/745

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
(8961103540SUC-TUBES-FN)				
Sterile & Non-Sterile Single Use Surgical Curettes (8961103540CURETTES-V7)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Scalpel Blade Handles (8961103540SCLPEL-BLADE-3B)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Ophthalmic Forceps (89611035SUOFC0300K4)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Ophthalmic Calipers (89611035SUOCP700AE)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Ophthalmic Hooks (89611035SUOHK500AQ)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Ophthalmic Needle Holders (89611035SUONH600CA)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Ophthalmic Scissors (89611035SUOSC400CL)	Class IIa	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Surgical Cannulas (89611035SUCAN1003G)	Class IIa	Sterile & Non-Sterile Surgical Cannulas	N/A	Certificate #PK19/818842621.01 NB1639
Sterile & Non-Sterile Single Use Redon Guide Needles (89611035SURDN200AR)	Class IIa	Sterile & Non-Sterile Single Use	N/A	Certificate #PK19/818842621.01 NB1639

GB NB1639 - Confirmation letter Regulation (EU) 2023/607

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
		Redon Needles		
Sterile Single Use Nasal Speculum (8961103540NASL-SPECULA-6T)	Class Is	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile Single Use Vaginal Speculum (8961103540VAG-SPECULA-UL)	Class Is	N/A	N/A	Certificate #PK19/818842621.01 NB1639
Sterile Single Use Ophthalmic Speculum (89611035SUOSP800G3)	Class Is	N/A	N/A	Certificate #PK19/818842621.01 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
Reusable General Surgical Instruments (Surgical Scissors, Surgical Forceps, Surgical Tweezers, Surgical Needle Holders, Surgical Retractors, Surgical Probes, Surgical Scalpel Blade Handles, Surgical Curettes,	Class Ir	N/A	N/A

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607

Bone Rongeurs/Cutting Forceps, Dilators, Trocars and Probes, Root Elevators, Extracting Forceps,			
Reusable General Surgical Instruments Surgical Cannulas/Suction Tubes)	Class Ir	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/25	Version 1	Initial issue
2024/09/06	Version 2	Addition of 1 x Class Is, 7 x Class IIa and Class Ir Devices

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607