Mercian Surgical Supply Co Ltd
10 Topaz Business Park
Topaz Way, Bromsgrove
Worcestershire
B61 0GD
UK

01/05/2024

Confirmation Letter Reference: CLNB1639 - GBPC 09262

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:

Mercian Surgical Supply Co Ltd
10 Topaz Business Park
Topaz Way, Bromsgrove
Worcestershire
B61 0GD
UK
SRN: GB-MF-000009797

Authorised Representative:

Advena Limited
Tower Business Centre, 2nd Floor
Tower Street
Swatar
BKR 4013
Malta.
SRN: MT-AR-000000234

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 [Jérôme JADOT]

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

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 Digiband Tourniquet 200mm 5060497070080	Class Is	Sterile Silicone Digiband Finger and Toe Tourniquets	N/A	GB19/964481; NB1639
Sterile Burs: Micro Rose Head Burs, Toller Taper Fissure TC Burs, Latch Burs, Round Head Burs Plain Cut, Flat Fissure Burs Cross Cut, Tapered Fissure Burs, Oval Trimmer Burs Plain Cut, Bud Trimmer Burs Cross Cut, CylinderTrimmer Burs Cross Cut, Lindemann Side Cutting Burs, Rosen ENT Cutting Burs, Round Head TC Burs Plain Cut, Allport ENT Cutting Burs, Polishing ENT Burs, Tapered Fissure TC Burs, Tapered Fissure TC Burs, Diamond ENT Burs, Tungsten Carbide ENT Burs, Diamond Abrasive Bud Burs 5060497070059	Class IIa	Sterile Surigical Burs and Saw Blades	N/A	GB19/964481; NB1639
Sterile Blades: Micro Compass Reciprocating Saw Blades, Micro Oscillating Saw Blade, Micro Sachse Osseoscalpel Saw Blades,	Class IIa	Sterile Surigical Burs and Saw Blades	N/A	GB19/964481; 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
Micro Sachse Sagittal Saw Blades 5060497070066				
Sterile Twist Drills: Round Fitting, AO Fitting, Cement twist drills, Oral surgery twist drills, triangular 5060497070097	Class IIa	Sterile orthopaedic surgical bone twist drills	N/A	GB19/964481; NB1639
Sterile Caspar Distraction Screws 5060497070073	Class IIa	Sterile Caspar Distraction Screws	N/A	GB19/964481; NB1639
Sterile Visibility Background Material 5060497070004	Class IIa	Sterile Visibility Background Material	N/A	GB19/964481; NB1639
Sterile Irrigation Tubing 5056126828061	Class IIa	Sterile Irrigation Tubing (For Micro Torque Surgical Drill System)	N/A	GB19/964481; NB1639
Micro Torque Drill System incorporating electronic control unit with irrigation, control footswitch, and Watson-Marlow pump unit 5056126865578 5056126865585 5056126865608	Class IIa	Micro Torque Surgical Drill System	N/A	GB19/964481; NB1639
Sterile K-Wires: Single Ended Trocar/Flat, D/E Trocar +Sterile Steinmann Pins:S/E	Class IIb	Sterile Kirschner Wires (K-	N/A	GB19/964481; 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
Fully Thread, S/E Denham Mid-Thread, D/E Fully thread 5060497070011 5060497070028 5060497070035 5060497070042		Wires) and sterile single use Steinmann and Denham Threaded Pins		

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: All their devices SGS is responsible for the SUR			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
01/05/2024	Version 1	Initial issue