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

23/10/24/2024

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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

Ian How
PP
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
Non Sterile Artery Forceps 5060497070004	Ir	Artery Forceps	N/A	GB19/964481; NB1639
Non Sterile Bone Punches 5060497070011	Ir	Bone Punches	N/A	GB19/964481; NB1639
Non Sterile Rongeurs 5060497070028	Ir	Rongeurs		GB19/964481; NB1639
Non Sterile Bone Nibbler 5060497070400	Ir	Bone Nibbler		GB19/964481; NB1639
Non Sterile Curettes 5060497070042	Ir	Curettes	N/A	GB19/964481; NB1639
Non Sterile Nipple Markers 5060497070059	Ir	Nipple Markers	N/A	GB19/964481; NB1639
Non Sterile Dilators 5060497070066	Ir	Dilators	N/A	GB19/964481; NB1639
Non Sterile Dissectors 5060497070073	Ir	Dissectors	N/A	GB19/964481; NB1639
Non Sterile Elevators 5060497070080	Ir	Elevators		GB19/964481; NB1639
Non Sterile Mallets 5060497070134	Ir	Mallets		GB19/964481; NB1639
Non Sterile Osteotomes 5060497070103	Ir	Osteotomes		GB19/964481; NB1639
Non Sterile Chisels 5060497070097	Ir	Chisels		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
Non Sterile Gouges 5060497070110	Ir	Gouges		GB19/964481; NB1639
Non Sterile Orthopaedic Impactors 5060497070127	Ir	Orthopaedic Impactors		GB19/964481; NB1639
Non Sterile Saws 5060497070165	Ir	Saws		GB19/964481; NB1639
Non Sterile Knives and Blades 5060497070158	Ir	Knives and Blades	N/A	GB19/964481; NB1639
Non Sterile Hooks 5060497070196	Ir	Hooks	N/A	GB19/964481; NB1639
Non Sterile Probes 5060497070202	Ir	Probes		GB19/964481; NB1639
Non Sterile Needle Holders 5060497070219	Ir	Needle Holders	N/A	GB19/964481; NB1639
Non Sterile Forceps 5060497070226	Ir	Forceps	N/A	GB19/964481; NB1639
Non Sterile Picks 5060497070233	Ir	Picks		GB19/964481; NB1639
Non Sterile Excavators 5060497070240	Ir	Excavators		GB19/964481; NB1639
Non Sterile Bone Awls 5060497070257	Ir	Bone Awls		GB19/964481; NB1639
Non Sterile Scissors 5060497070264	Ir	Scissors		GB19/964481; NB1639
Non Sterile Rasps 5060497070295	Ir	Rasps		GB19/964481; NB1639
Non Sterile Speculums 5060497070349	Ir	Speculums		GB19/964481; NB1639
Non Sterile Bone Tampers 5060497070356	Ir	Bone Tampers		GB19/964481; NB1639
Non Sterile Tendon Strippers 5060497070363	Ir	Tendon Strippers		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
Non Sterile Wire Cutter 5060497070387	Ir	Wire Cutter	N/A	GB19/964481; NB1639
Non Sterile Pliers 5060497070394	Ir	Pliers	N/A	GB19/964481; NB1639
Retractors 5060497070271	Class IIa	Retractors	N/A	GB19/964481; NB1639
Cannulas 5060497070288	Class IIa	Cannulas	N/A	GB19/964481; NB1639
Vascular Clamps 5060497070370	Class IIa	Vascular Clamps	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	Class IIa	Sterile Surigical Burs	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
Blade, Micro Sachse Osseoscalpel Saw Blades, Micro Sachse Sagittal Saw Blades 5060497070066		and Saw Blades		
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

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 K-Wires: Single Ended Trocar/Flat, D/E Trocar +Sterile Steinmann Pins:S/E Fully Thread, S/E Denham Mid-Thread, D/E Fully thread 5060497070011 5060497070028 5060497070035 5060497070042	Class IIb	Sterile Kirschner Wires (K-Wires) and sterile single use Steinmann and Denham Threaded Pins	N/A	GB19/964481; 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: 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

23/10/2024	Version 2	Client request to include the devices below in their MDR scope: Class Ir devices: Non Sterile Artery Forceps 5060497070004 Non Sterile Bone Punches 5060497070011 Non Sterile Rongeurs 5060497070028 Non Sterile Bone Nibbler 5060497070400 Non Sterile Curettes 5060497070042 Non Sterile Nipple Markers (class Is) 5060497070059 Non Sterile Dilators 5060497070066 Non Sterile Dissectors 5060497070073 Non Sterile Elevators 5060497070080 Non Sterile Mallets 5060497070134 Non Sterile Osteotomes 5060497070103 Non Sterile Chisels 5060497070097 Non Sterile Gouges 5060497070110 Non Sterile Orthopaedic Impactors 5060497070127 Non Sterile Saws 5060497070165 Non Sterile Knives and Blades 5060497070158 Non Sterile Hooks 5060497070196 Non Sterile Probes 5060497070202 Non Sterile Needle Holders 5060497070219

		Non Sterile Forceps 5060497070226 Non Sterile Picks 5060497070233 Non Sterile Excavators 5060497070240 Non Sterile Bone Awls 5060497070257 Non Sterile Scissors 5060497070264 Non Sterile Rasps 5060497070295 Non Sterile Speculums 5060497070349 Non Sterile Bone Tampers 5060497070356 Non Sterile Tendon Strippers 5060497070363 Non Sterile Wire Cutter 5060497070387 Non Sterile Pliers 5060497070394 Class IIa: Retractors 5060497070271 Cannulas 5060497070288 Vascular Clamps 5060497070370