Meditech Systems Ltd
Unit 3 Shrublands Estate
Shaftesbury, Dorset
SP7 9PT
UK

22/05/2024

Confirmation Letter Reference: CLNB1639 - GBPC 08743

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:

Meditech Systems Ltd
Unit 3 Shrublands Estate
Shaftesbury, Dorset
SP7 9PT
UK
SRN: UK-MF-000040287

Authorised Representative:

Clowrey Consultancy
White House at Bridge,
Holycross Village,
Thurles,
County Tipperary,
E41 EC65,
Eire
SRN: IE-AR-000037040

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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
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Global Medical Device Certification Manager
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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
MEDIZIP 50552767MEDIZIP01FT	Class Is	Sterile single-use non-invasive medical instruments & instrument sets	N/A	GB19/964768; NB1639
SCRATCH PAD 50552767SCRATCHPAD01WF	Class Is	Sterile & non-sterile single use electrosurgical scratch pads	N/A	
BOUGIE 50552767BOUG01GQ	Class Is	Sterile single-use orophyrangeal, nasophyrangeal airways and bougies	N/A	
ELECTROSURGERY CABLES 50552767ECABLES01X5	Class Is	Sterile single-use monopolar & bipolar electrosurgical cables	N/A	
AEROSOL TUBE 50552767AEROTUBE0132	Class IIa	Non-sterile single-use aerosoltube for oxygen, air, humidification delivery and scavenging	N/A	
AIRWAY CONNECTORS 50552767BSCONNECT01TK	Class IIa	Non-sterile single-use anaesthesia and respiratory components	N/A	
APL VALVES_ PEEP VALVE 50552767PEEPAPLVLV01YF	Class IIa	Non-sterile single-use PEEP valves and breathing system vavles	N/A	

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
Rapid O2 50552767RAPIDO201CM	Class IIa	Non-sterile single-use cricothyroidotomy insufflation device Sterile single-use cricothyroidotomy insufflation tubing set	N/A	
BREATHING SYSTEM ELECTROSTATIC FILTERS 50552767BSFILTERS01WN	Class IIa	Non-sterile single-use reading system filters {HEPA filter, HME filter, Electrostatic filter, CO2 monitoring line filter) Sterile single-use reading system filters {HEPA filter, HME filter, Electrostatic filter, CO2 monitoring line filter)	N/A	

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
BREATHING SYSTEM HEPA FILTERS 50552767BSFILTERS01WN	Class IIa	Non-sterile single-use reading system filters {HEPA filter, HME filter, Electrostatic filter, CO2 monitoring line filter) Sterile single-use reading system filters {HEPA filter, HME filter, Electrostatic filter, CO2 monitoring line filter)	N/A	
Breathing Sets 50552767BREATHSET01RS	Class IIa	Sterile single-use breathing systems Non-sterile single-use breathing systems Non-sterile re-usable breathing systems	N/A	
CATHETER MOUNTS 50552767CATHMOUNT01U3	Class IIa	Sterile single-use breathing systems Non-sterile single-use breathing systems	N/A	
Insufflation Tubing Set 50552767INSUFFSET01AQ	Class IIa	Single-use insufffation tube and filter sets	N/A	

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
Capno Guard Bite Block 50552767BITEBLOCK01JA	Class IIa	Non-sterile single-use oxygen tubes, nasal cannula and bite blocks	N/A	
Nasal cannula 50552767NCANNULA01ZS	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
AEROSOL MASKS 50552767OXYMASKS01U8	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
OXYGEN MASKS 50552767OXYMASKS01U8	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
OXYGEN TRACHEOSTOMY MASKS 50552767OXYMASKS01U8	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
OXYGEN NON-REBREATHING MASKS 50552767OXYMASKS01U8	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
OXYGEN CO2 MASKS (aka CAPNOGRAPHY OXYGEN MASK) 50552767CO2MASK01XV	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
OXYGEN NEBULISER MASK KIT 50552767NEBMASKS01XW	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
OXYGEN NEBULISER MASK KIT WITH MOUTHPIECE 50552767NEBMASKS01XW	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	

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
OXYGEN VENTURI MASKS & MASK KITS 50552767VENTUMSK01QN	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
Venturi Jets 50552767VENTJETS01JW	Class IIa	Non-sterile single-use air entrainment venturi jets	N/A	
Oxygen Tube 50552767OXYTUBES01YW	Class IIa	Non-sterile single-use oxygen delivery masks and masked sets	N/A	
RESERVOIR BAGS 50552767RESBAGS01FY	Class IIa	Non-sterile single-use and re-usable anaesthesia reservoior bags	N/A	
T BAG 50552767TBAGS01MB	Class IIa	Sterile single-use breathing systems Non-sterile single-use breathing systems	N/A	
Heated Wire Breathing Sets 50552767HEATWBS01	Class IIa	Sterile single-use breathing systems Non-sterile single-use breathing systems	N/A	

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
ELECTROSURGERY FORCEPS 50552767EFORCEPS01XX	Class IIb	Sterile single-use electrosurgery monopolar and bipolar forceps Sterile re-usable electrosurgery monopolar and bipolar forceps Non-sterile single-use monopolar and monopolar and bipolar electrosurgery forceps Non-sterile re-usable elecfrosurgery monopolar and bipolar forceps	N/A	

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	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
22/05/2024	Version 1	Initial issue