Rossmax Swiss GmbH
Widnauerstrasse 1, CH-9435 Heerbrugg, Switzerland

<2023/06/09>

Confirmation Letter Reference: CLNB1639 - TW/TPE/VW604603

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:

Manufacturer: Rossmax Swiss GmbH
Widnauerstrasse 1,
Heerbrugg,
Switzerland
SRN Number (if available): CH-MF-000011245

Authorized representative: CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo N18,
Málaga,
Spain
SRN Number (if available): ES-AR-000000293

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

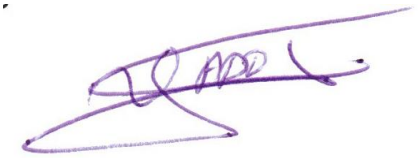
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired prior to the publication of the Regulation EU 2023/607 on 15th March 2023, this letter also confirms that:

- The 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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 manufacturer submitted the MDR application and signed the written agreement by the date of MDD/AIMDD certificate expiry (22nd May 2023);

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]

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Global Medical Device Certification Manager
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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
Non-invasive blood pressure measuring device Basic UDI-DI: 4715139BPMD9	Class IIa Upper arm blood pressure monitor	N/A	Certificate TW19/20056; NB1639
Non invasive blood pressure measuring device with pulse arrhythmia detecting function (includes AFib (Atrial Fibrillation), PC (Premature Contraction), TACH (Tachycardia) and BRAD (Bradycardia) Basic UDI-DI: 4715139BPMPARRX4	Class IIa Upper arm blood pressure monitor with PARR function Z5,X5,C5	N/A	Certificate TW19/20056; NB1639
Non-invasive blood pressure measuring device Basic UDI-DI: 4715139BPMHSDUR	Class IIa Upper arm blood pressure monitor with resting detection function AD761f	N/A	Certificate TW19/20056; NB1639
Non invasive blood pressure measuring device with pulse arrhythmia detecting function (includes AFib (Atrial Fibrillation), PC (Premature Contraction), TACH (Tachycardia) and BRAD (Bradycardia) Basic UDI-DI: 4715139BPMClinical5J	Class IIa Upper arm blood pressure monitor with PARR function (professional) X9, AC1000f	N/A	Certificate TW19/20056; 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
Non-invasive blood pressure measuring device Basic UDI-DI: 4715139BPMWristS5	Class IIa Wrist blood pressure monitor	N/A	Certificate TW19/20056; NB1639
Infrared ear/temple thermometer Basic UDI-DI: 4715139IREar2K	Class IIa Infrared ear thermometer RA600,RB600	N/A	Certificate TW19/20056; NB1639
Infrared ear/temple thermometer Basic UDI-DI: 4715139IRTemple3S	Class IIa Temple thermometer (non-contact) HA500,HB500,HD500	N/A	Certificate TW19/20056; NB1639
Infrared ear/temple thermometer Basic UDI-DI: 4715139IRTempleHCSD	Class IIa Temple thermometer (non-contact) (professional) HC700	N/A	Certificate TW19/20056; NB1639
Powered suction unit Basic UDI-DI: 4715139SuctionB4	Class IIa Suction unit V3, V5, V7	N/A	Certificate TW19/20056; NB1639
Nebulizer (including nebulizer pack and nebulizer bottle set) for respiratory therapy	Class IIb excluding Class	N/A	Certificate TW19/20056; 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
Basic UDI-DI: 4715139NEBDE	IIb implantable non-WET Piston nebulizer		
Nebulizer (including nebulizer pack and nebulizer bottle set) for respiratory therapy Basic UDI-DI: 4715139NEB3in1UQ	Class IIb excluding Class IIb implantable non-WET Multifunction Piston nebulizer NK1000	N/A	Certificate TW19/20056; NB1639
Nebulizer (including nebulizer pack and nebulizer bottle set) for respiratory therapy Basic UDI-DI: 4715139NEBMesh57	Class IIb excluding Class IIb implantable non-WET Mesh nebulizer NC200	N/A	Certificate TW19/20056; NB1639

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/06/09	Version 1	Initial issue
2023/06/18	Version 2	Contents updated
2023/06/19	Version 3	Contents updated