Ningbo Shengyurui Medical Appliances Co., Ltd.
No.138 Binhaisi Road, Hangzhou Bay Zone, Ningbo City,
Zhejiang Province, 315336
P.R.China

2024/03/11

Confirmation Letter Reference: CLNB1639 - CN/NGB/5495

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

Ningbo Shengyurui Medical Appliances Co., Ltd.
No.138 Binhaisi Road, Hangzhou Bay Zone, Ningbo City,
Zhejiang Province,315336
P.R.China
SRN Number: CN-MF-000026643

Authorized representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestrasse 80,20537 Hamburg,
Germany
SRN Number: DE-AR-000000001

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93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.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 1639,

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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)	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 Nasal Cannula Basic UDI-DI: 69450993NOC001R8	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Oxygen Mask with Reservoir Bag Basic UDI-DI: 69450993OMB001QQ	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Simple Oxygen Mask Basic UDI-DI: 69450993SOM001VF	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Nebulizer Mask Basic UDI-DI: 69450993NMK001SA	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Venturi Mask Basic UDI-DI: 69450993VMK001VJ	Class IIa	N/A	Certificate CN19/41067 NB 1639
Sterile and non sterile Suction Connection Tube with Yankauer Handle Basic UDI-DI: 69450993STB001UR	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Tracheostomy Mask Basic UDI-DI: 69450993TMK001UQ	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Jet Nebulizer Set	Class IIa	N/A	Certificate CN19/41067 NB 1639

Device name or 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: 69450993JNS001SR			
Non sterile Anaesthetic Mask Basic UDI-DI: 69450993AMK001LZ	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Non invasive Positive Pressure Ventilation Mask Basic UDI-DI: 69450993PPV001WJ	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Capno CO_2 Mask Basic UDI-DI: 69450993CPC001M4	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Capno CO_2 Nasal Cannula(including Capno O_2/ CO_2 Nasal, Cannula and Capno CO_2 Sampling Nasal Cannula Basic UDI-DI: 69450993CNC001LE	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Breathing Circuit (including Dual limb breathing circuit, Single limb breathing circuit, J circuit, Dual limb breathing circuit with catheter mount, and accessories of HME, HMEF, BV Filter, HEPA Filter) Basic UDI-DI:	Class IIa	N/A	Certificate CN19/41067 NB 1639

Device name or 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
69450993BCT001KX			
Non sterile Electrostatic adsorption film Bacteria Filter(including BV Filter, PFT Filter, HMEF, HEPA Filter) Basic UDI-DI: 69450993EBF001HR	Class IIa	N/A	Certificate CN19/41067 NB 1639
Non sterile Anaesthetic breathing circuit(including Circuit and accessories of Gas Sampling Line, BV Filter, Breathing Bag) Basic UDI-DI: 69450993ABC001FG	Class IIa	N/A	Certificate CN19/41067 NB 1639

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
2024/03/11	Version 1	Initial issue

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	**Ningbo Shengyurui Medical Appliances Co., Ltd**
Manufacturer address and contact details	No.138 Binhaisi Rd., Hangzhou Bay New Zone, Ningbo City, Zhejiang Province, China
Single Registration Number (SRN) (if available)	CN-MF-000026643

Authorised Representative name (if applicable)	**Shanghai International Holding Corp. GmbH (Europe)**
Authorised Representative address and contact details	Eiffestrasse 80, 20537 Hamburg，Germany
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	**SGS Belgium NV**
Notified body number (if applicable)	CE1639
Directive Certificate number(s) to which this confirmation is made (if applicable)	CN19/41067
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-03-08
End date of extended validity/transition period	2024-09-26

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

  ☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

☒Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☑ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name Ningbo Shengyurui Medical Appliances Co., Ltd

Location & Date China,2023-10-09

Signature, Print Name, Title QA Manager, Linna Luo

Contact Details (at least email) ZJ@soundway-medical.com

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Declaration, including the attached schedule, should be printed on form as used for a Declaration of Conformity per manufacturer's QMS (e.g. manufacturer's letterhead)

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Simple Oxygen Mask (include 1041S/1049S/ 41035S/41040S/41042S/41050S)	CN19/41067	2024-03-08	SGS Belgium CE1639	SGS Belgium CE1639	2028-12-30	
Oxygen Mask with Reservoir Bag (include 1059S/41007S/41058S /41060S/41069S)	CN19/41067	2024-03-08	SGS Belgium CE1639	SGS Belgium CE1639	2028-12-30	
Tracheostomy Mask (include 1075S/41076S)	CN19/41067	2024-03-08	SGS Belgium CE1639	SGS Belgium CE1639	2028-12-30	
Nasal Cannula (include 1103P/1104P)	CN19/41067	2024-03-08	SGS Belgium CE1639	SGS Belgium CE1639	2028-12-30	
Nebulizer Mask (include 1083S/41085S)	CN19/41067	2024-03-08	SGS Belgium CE1639	SGS Belgium CE1639	2028-12-30	
Venturi Mask (include 41098S)	CN19/41067	2024-03-08	SGS Belgium CE1639	SGS Belgium CE1639	2028-12-30	

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

EC Certificate Full Quality Assurance System: Certificate CN19/41067

The management system of

Ningbo Shengyurui Medical Appliances Co., Ltd.

No. 138, Binhaisi Road, Hangzhou Bay New Zone,
315336, Ningbo, Zhejiang Province, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 08 March 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1, Certified since 19 November 2009
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CN/NGB 5495

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Ningbo Shengyurui Medical Appliances Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

**Sterile and non sterile Simple Oxygen Mask,
Sterile and non sterile Oxygen Mask with Reservoir Bag,
Sterile and non sterile Nebulizer Mask,
Sterile and non sterile Nasal Cannula,
Sterile and non sterile First Aid Mask,
Sterile and non sterile Venturi Mask,
Sterile and non sterile Medical Valves Series (including Three Way Stopcock, Sterile and non sterile Two Way Stopcock, Sterile and non sterile Three Way Stopcock with Extension Tube, Extension Tube),
Sterile and non sterile Suction Connection Tube with Yankauer Handle,
Sterile and non sterile Tracheostomy Mask,
Sterile and non sterile Jet Nebulizer Set,
Sterile and non sterile Anaesthetic Mask,
Sterile and non sterile Non invasive Positive Pressure Ventilation Mask,
Oxygen Flow Metering device,
Sterile and non sterile Capno CO_2 Mask,
Sterile and non sterile Capno CO_2 Nasal Cannula (including Capno O_2/CO_2 Nasal Cannula and Capno CO_2 Sampling Nasal Cannula),
Sterile and non sterile Two Way Manifold,
Sterile and non sterile Breathing Circuit (including Dual limb breathing circuit, Single limb breathing circuit, J circuit, Dual limb breathing circuit with catheter mount, and accessories of HME, HMEF, BV Filter, HEPA Filter),
Sterile and non sterile Electrostatic adsorption film Bacteria Filter (including BV Filter, PFT Filter, HMEF, HEPA Filter),
Sterile and non sterile Anaesthetic breathing circuit (including Circuit and accessories of Gas Sampling Line, BV Filter, Breathing Bag)**

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.