EC Certificate Production Full Quality Assurance System: Certificate CN19/41056

The management system of

# Dongguan Aidisy Machinery & Electronic Equipment Co., Ltd.

Part B, 3rd F, Block A, Wentang Industrial Park, Longhua Road, Zhouwu, Dongcheng District, Dongguan City, Guangdong Province, 523118, P.R. China

has been assessed and certified as meeting the requirements of

# Directive 93/42/EEC

**on medical devices, Annex V**

For the following products

**Compressor Nebulizer for Conscious Patient of Asthma Treatment Models: MCN-S600A, MCN-S600B, MCN-S600C, MCN-S600D, MCN-S600E, MCN-S600F, MCN-S600G, MCN-S600MA, MCN-S600MB, MCN-S600MC, MCN-S600MD, MCN-S600ME, MCN-S600MF, MCN-S600MG, MCN-S600MH, MCN-S600MI**

**DC Compressor Nebulizer for Conscious Patient of Asthma Treatment Models: MCN-DS600A, MCN-DS600B, MCN-DS600C, MCN-DS600D, MCN-S600E**

**Portable (Ultrasonic) Nebulizer for Conscious Patient of Asthma Treatment Models: Mesh-S600A, Mesh-S600B, Mesh-S600C, Mesh-S600D**

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

This certificate is valid from 11 May 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 18 September 2018

Certification is based on reports numbered CN/DGG/ 11786

Authorised by

Global Medical Devices Head of Notified Body

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

**Dongguan Aidisy Machinery & Electronic Equipment Co., Ltd.**
**Part B, 3rd F, Block A, Wentang Industrial Park, Longhua Road, Zhouwu, Dongcheng District, Dongguan City, Guangdong Province, 523118, P.R. China**

Dec-21,2023

**Confirmation Letter Reference: CLNB1639 - CN/DGG11786**

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:

**Dongguan Aidisy Machinery & Electronic Equipment Co., Ltd.**
**Part B, 3rd F, Block A, Wentang Industrial Park, Longhua Road, Zhouwu, Dongcheng District, Dongguan City, Guangdong Province, 523118,**
**P.R. China**
**SRN Number: CN-MF-000026848**

**Authorized representative:**
**MedPath GmbH**
**Mies-van-der-Rohe-Strasse 8,**
**80807 Munich,**
**Germany**

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 manufacturer submitted the MDR application and signed the written agreement 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,

pp [Haldun OGUZ]

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

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 |
|---|---|---|---|
| **Compressor Nebulizer for Conscious Patient of Asthma Treatment Models: MCN-S600A, MCN-S600B, MCN-S600C, MCN-S600D, MCN-S600E, MCN-S600F, MCN-S600G, MCN-S600MA,** | **Class IIa** | **N/A** | **Certificate CN19/41056; NB 1639** |

| 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 |
|---|---|---|---|
| **MCN-S600MB, MCN-S600MC, MCN-S600MD, MCN-S600ME, MCN-S600MF, MCN-S600MG, MCN-S600MH, MCN-S600MI**<br><br>**Basic UDI DI: 69571303MCN0001GX** | | | |
| **DC Compressor Nebulizer for Conscious Patient of Asthma Treatment Models: MCN-DS600A, MCN-DS600B, MCN-DS600C, MCN-DS600D, MCN-DS600E**<br><br>**Basic UDI DI: 69571303MCN0001GX** | **Class IIa** | **N/A** | **Certificate CN19/41056; NB 1639** |
| **Portable (Ultrasonic) Nebulizer for Conscious Patient of Asthma Treatment Models: Mesh-S600A, Mesh-S600B, Mesh-S600C, Mesh-S600D**<br><br>**Basic UDI DI: 69571303MESH001QH** | **Class IIa** | **N/A** | **Certificate CN19/41056; NB 1639** |

Confirmation Letter Revision History

| Date | NB internal reference traceable to each version of the letter | Action |
|---|---|---|
| 2023/12/21 | Version 1 | Initial issue |