EU Quality Management System Certificate CN26/00001566

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
SRN Number: CN-MF-000026848

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 10 March 2026 until 10 March 2031 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 10 September 2030

Issue 1. Certified since 10 March 2026

Authorised by
Virginie Siloret
Head of Certification and Compliance

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EU Quality Management System Certificate
CN26/00001566, continued

Dongguan Aidisy Machinery & Electronic Equipment Co., Ltd.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIa device
MDA0307
Compressor Nebulizer for aerosolize physician-prescribed solutions for inhalation (Models: MCN-DS600A, MCN-DS600B, MCN-DS600C, MCN -DS600D, MCN-DS600E, 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)
Basic UDI-DI: 69571303MCN0001GX

MDA0307 MDS1009
Portable (Ultrasonic) Nebulizer for Conscious Patient of Asthma Treatment (Models: Mesh-S600A, Mesh-S600B, Mesh-S600C, Mesh-S600D)
Basic UDI-DI: 69571303MESH001QH

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - CN/DGG/288229 - S2A 1.0 + TFR 1.2
Authorized representative name and address (if relevant): MedPath GmbH; Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
Previous certificate number: N/A
Change in between this certificate and previous one: N/A

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