

EU Quality Management System Certificate TW23/00000774

The management system of

ASIA CONNECTION CO., LTD.

16F-1, No. 16, Jian Ba Road, Chung Ho District, New Taipei City, 235603, Taiwan
SRN Number: TW-MF-000006739

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

- Class IIa MDA0306 –

Powered nasal aspirator for alleviation of nasal discomfort (Model: ME8202X)
Basic UDI-DI 471987228ME8202XG4

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: TW/TPE/614024 - S2A 1.2

Authorized representative Name and address (if relevant): Advena Limited, Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

This certificate is valid from 13 October 2023 until 13 October 2028 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 April 2028

Issue 1. Certified since 13 October 2023

Certified activities performed by additional sites are listed on subsequent pages.



Authorised by

Virginie Siloret

Global Medical Device Certification
Manager

SGS Belgium NV NB 1639

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ASIA CONNECTION CO., LTD.

MDR EU Quality Management System certificate (Annex IX QMS)

Issue 1
Sites
ASIA CONNECTION CO., LTD. 16F-1, No. 16, Jian Ba Road, Chung Ho District, New Taipei City, 235603, Taiwan
ASIA CONNECTION CO., LTD. 8F-4, No. 16, Jian Ba Road, Chung Ho District, New Taipei City, 235603, Taiwan
ASIA CONNECTION CO., LTD. 18F-4, No.16, Jian Ba Road, Chung Ho District, New Taipei City, 235603, Taiwan

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