



Declaration of Conformity

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices.

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Powered Nasal Aspirator
Legal Manufacturer: (Name on Label)	Asia Connection Co., Ltd. 16F-1, No. 16, Jian Ba Road, Chung Ho District, New Taipei City 235603, Taiwan
Manufacturers SRN:	TW-MF-000006739
Basic UDI-DI:	471987228ME8202XG4
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Powered Nasal Aspirator is intended to provide intermittent suction for removing nasal secretions and mucus to alleviate nasal discomfort.
MDR Classification:	Class IIa(Annex VIII, Rule 12)
Notified Body:	SGS Belgium NV(Identification Number 1639)
EC Certificate:	TW23/00000774
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	in accordance with Annex IX of Regulation (EU) 2017/745 conformity assessment based on a quality management system and on assessment of technical documentation

Name John Lee **Position** Person Responsible For Regulatory Compliance(PRRC)

Signed  **Date** October 23rd, 2024 **Place** New Taipei City, Taiwan

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



Appendix I – Applicable Standards

This present declaration is also in conformity with the following standards and Common Specifications (CS):

- EN ISO 13485:2016
- EN ISO 14971:2019+A11:2021
- EN ISO 15223-1:2021
- EN ISO 20417:2021
- EN 60601-1:2006+A2:2021
- EN 60601-1-2:2015+A1:2021
- EN 60601-1-6:2010+A2:2021(EN 62366-1:2015+A1:2020)
- EN 60601-1-11:2015+A1:2021
- EN ISO 10993-1:2020
- EN ISO 10993-5:2009
- ISO 10993-10:2021
- EN ISO 10993-23:2021
- EN ISO 10993-17:2009
- EN ISO 10993-18:2020
- EN ISO 17664-1:2021

Appendix II – Product Listing/Schedule

Part / Catalogue Number	Description/Name	GMDN Code
ME8202X	Powered Nasal Aspirator	41599

Appendix III – Photo of Product





Version History

Version	Compiled by	Date	Description
A	John Lee	September 30th, 2022	Initial Version
B	John Lee	May 10th, 2023	The following parts are updated to close TCAR issued by TD reviewer during TD initial review: 1. Intended Purpose updated 2. Applicable Standards updated 3. Photo of Products added
C	John Lee	October 18th, 2023	Updated with EC Certificate Number and PRRC's signature
D	John Lee	October 23rd, 2024	1. Add the sole responsibility statement 2. Add version history section