

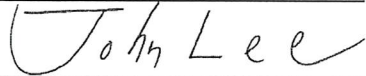


## Declaration of Conformity

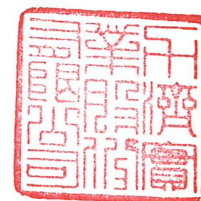
**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states.**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Powered Nasal Aspirator
Legal Manufacturer:	Asia Connection Co., Ltd. 16F-1, No. 16, Jian Ba Road, Chung Ho District, New Taipei City 235603, Taiwan
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Powered Nasal Aspirator is intended to remove excess mucus from a patient's nostril for alleviation infection of upper respiratory tract.
MDD Classification:	Class IIa (Annex IX, Rule 11)
Notified Body:	SGS Belgium NV
CE Certificate Reference:	TW19/20059
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD Conformity Assessment Route:	EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Full Quality Assurance in accordance with Annex II (excluding section 4) of the Medical Device Directive

Name John Lee Position Manager  
Signed  Date July 6th, 2022 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 European standards and Common Specifications:

- EN ISO 13485:2016
- EN ISO 14971:2012
- EN ISO 15223-1:2016
- EN 1041:2008
- EN 60601-1:2006+AC:2010 + A11: 2011 + A1: 2013
- EN 60601-1-2:2015
- EN 60601-1-6:2010+A1:2015(IEC 62366-1:2015)
- EN 60601-1-11:2010
- EN ISO 10993-1:2009+AC2010
- EN ISO 10993-5:2009
- ISO 10993-10:2010

## Appendix II – Product Listing/Schedule

Part / Catalogue Number	Description/Name	GMDN Code
ME8202X	Powered Nasal Aspirator	41599
BC50	Electric Nasal Aspirator Brand: Microlife	41599