



Pu Yuan Biotech Co.,LTD
4F.,4F.-1, No. 51, Ln. 35,Jihu Rd., Neihu Dist.,
Taipei City 11492,Taiwan(R.O.C)
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CE 1639

EC DECLARATION OF CONFORMITY

MANUFACTURER NAME:

PU YUAN BIOTECH CO., LTD

BUSINESS ADDRESS:

4F.,4F.-1, No. 51, Ln. 35,Jihu Rd., Neihu Dist.,Taipei City 11492,Taiwan(R.O.C)

PRODUCT NAME:

Nebulizer (including mouthpiece and mask)

PRODUCT CODE:

Azmaler-2

PRODUCT DESCRIPTION:

Microlife NEB 800

CERTIFICATE NUMBER:

TW19/20047 or its update

CLASSIFICATION:

Council Directive 93/42/EEC, Annex II (excluding section 4) on Medical Devices Class II a (rule 11) for main unit & medical cup and Class IIa (rule 2) for mask & mouth piece

DECLARATION:

We here declare that the above mentioned products comply with the requirements set out in the Council Directive on the harmonization of the laws of Member States concerning Annex II, Section 3 of the Directive 93/42/EEC on Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

EC REPRESENTATIVE:

OBELIS S.A

Bd. Général Wahis, 53 1030 Brussels, Belgium

NOTIFIED BODY:

SGS Belgium NV

SGS House - Noorderlaan 87 Antwerp, 2030, Belgium

Person responsible for making this declaration:

Position / Name

General Manager / Evan Chuang

Legal Signature

Date: Mar. 20, 2025

