EC Certificate Full Quality Assurance System: Certificate TW13/10734

The management system of

Pu Yuan Biotech Co., LTD.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Nebulizer for respiratory therapy of conscious patient.
Model:
PY-001, PY-002, PY-004, PY-005, PY-005A, PY-006, PY-007, Azmaler-2

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 03 September 2018 until 02 September 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 07 March 2019
Issue 5. Certified since 26 April 2011

Certification is based on reports numbered TW/TPE K604030

Authorised by

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