

EC Declaration of Conformity

Manufacturer:

APEX MEDICAL CORP.
No. 9, Min Sheng St., Tu-Cheng, New Taipei City, 23679, Taiwan, R.O.C.

whose single Authorized Representative:

APEX MEDICAL S.L.

Elcano 9, 6 a planta 48008 Bilbao. Vizcaya

SPAIN

Tel: (+34) 94.470.64.08

We, the manufacturer, herewith declare that the products

Suction Pumps (UMDNS Code: 10208) Suction Pumps (GMDN Code: 36777)

Model Number(型號):

TC-2000V · VC-701 · Vac Pro · Vac Maxi · Vac Plus

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to **Annex II, excluding Section 4** of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany

> Certificate No.: HD 1623480-1 Effective date: 2021.05.06 Expiry date: 2024.05.26

following the procedure relating to the EC Declaration of Conformity set out in **Annex II**, **excluding Section 4** of Directive 93/42/EEC.

This Declaration of conformity is valid in connection with the release document for the respective serial of produced devices.

The above mentioned declaration of conformity is exclusively under the responsibility of

APEX MEDICAL CORP.

Taipei, MAY.06, 2021

Place, date

Mark Lin

Director of Quality Division Legally binding signature, Function

EC Declaration of Conformity