

## 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<sup>a</sup> planta 48008 Bilbao. Vizcaya  
SPAIN  
Tel: (+34) 94.470.64.08

We, the manufacturer, herewith declare that the products

*CPAP Mask (UMDNS Code: 12447)*

*CPAP Mask-face mask (GMDN Code: 57814)*

*CPAP Mask-nasal mask (GMDN Code: 57815)*

**Model Number(型號):**

668041-0000 、 668042-0000 、 668043-0000 、 668058-0000 、 668059-0000 、 668060-0000 、  
668044-0000 、 668045-0000 、 668054-0000 、 668061-0000 、 668062-0000 、 668063-0000 、  
WiZARD 210 、 WiZARD 220 、 WiZARD 230 、 WiZARD 310 、 WiZARD 320 、 WiZARD 510 、  
WiZARD 520 、 WiZARD 330

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

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



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