

## 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

***Air Mattress, Compression Sleeves, Cushions and Pumps (UMDNS Code: 18147)***

***Air Mattress, Compression Sleeves, Cushions and Pumps (GMDN Code: 47478)***

***Model Number(型號):***

***Domus 1 : 9C0470D4***

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 60129751 0001**

Effective date: **26.06.2018**

Expiry date: **25.06.2023**

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.24, 2019  
Place, date

Andrea Chen  
Manager of Quality Management Department  
Legally binding signature, Function