

## 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):*

9P-046XXX : PM100 series/Domus 2+/Verso

9P-074500/9P-074540/9P-077000 : Domus 3

9P-077540 : Domus 3D

9P-051500 : Pro-care 2

9P-052500 : Pro-care 3/4/Bariatric (V1)

9P-052080 : Pro-care Auto (V1)

9P-052580 : Pro-care Auto (V1/V2), Pro-care Auto Bariatric (V2)

9P-077520 : Domus Auto, Domus Auto (2019), Domus Auto Bariatric

9P-085500 : Pro-care Turn (Optima Turn)

9P-086520/9P-086530 : Pro-care Optima(Prone), Optima Auto, Optima Auto Link, Optima Prone

9P-087500 : Pro-care 4 (G2)

9P-087520 : Pro-care Auto (G2), Pro-care Auto Bariatric (G2), Pro-care Auto Pediatric

9P-079000/9P-079020/9P-079040 : Serene, Serene Bariatric

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, Feb.15, 2023

Place, date

Mark Lin

Director of Quality Division

Legally binding signature, Function