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

Air Mattress, Compression Sleeves, Cushions and Pumps (UMDNS Code: 17757)
Air Mattress, Compression Sleeves, Cushions and Pumps (GMDN Code: 47478)
Model Number:
9P-046500: PM100A, 9P-046520: DOMUS 4, 9P-047580: DOMUS 1, 2,
9P-048540: COMBO 100 PLUS, 9P-048560: Sedens 500,
9P-051500: Pro-care 2, 9P-052500: Pro-care 3, 4, Bariatric
9P-052580: Pro-care Auto, 9P-074540: DOMUS 3,
9P-077000: DOMUS 4, 9P-077520: DOMUS Auto, 9P-079000: Serene

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 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.

Alan Wu
Director of Quality Management Division
Legally binding signature, Function

Taipei, Jun.29, 2016
Place , date