

EC Declaration of Conformity

Manufacturer: Shenzhen Caremed Medical Technology Co., Ltd.
Address: East side, 3/F, C building, Kelunte low-carbon industries park, Gaofeng Community, Dalang office, Longhua district, 518109/Shenzhen, People's Republic of China

EC-Representative: SUNGO Europe B.V
Address: Olympisch Stadion 24, 1076DE Amsterdam

We declare under our sole responsibility that

Products: ECG electrode

Model: AD-BW-10(DH 849915)

(Compatible model: For general use)

GMDN Code: 61821

Basic UDI-DI: 69707585ECG01QK

Class: I

according to According to Rule 13, Annex VIII, Regulation (EU) 2017/745

meet the provisions of the Regulation (EU) 2017/745 and its transpositions in national laws which apply to it.

Conformity assessment procedure:

Annex II+III of Regulation (EU) 2017/745

EN ISO13485:2016:

TÜV SÜD Product Service GmbH
Ridlerstraße65, 80339, München, Germany
Certificate No.: Q5 088955 005 Rev.03
Valid from: 2022-03-03
Valid until: 2024-02-09

The CE Mark:



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

Company: Shenzhen Caremed Medical Technology Co., Ltd.

Address: East side, 3/F, C building, Kelunte low-carbon industries park, Gaofeng Community, Dalang office, Longhua district, 518109/Shenzhen, People's Republic of China

2022/3/30
ShenZhen,
Place, Date



Legally binding signature, Function