

EU Declaration of Conformity

CE MDR Registration No. : HZ 2111011-1

Manufacturer:

Shenzhen Combei Technology Co., Ltd.

11-5B, No. 105, Huanguan South Road, Dahe
Community, Guanhu Street, Longhua District
Shenzhen 518110 Guangdong, P.R.China

Authorized representative:

MedNet EC-REP GmbH

Borkstrasse 10, 48163 Munster, Germany

EUDAMED Single Registration Number: SRN: CN-MF-000016047

SRN: DE-AR-000000002

Products: Products of class IIa

EMDN code Z12030205 - NON-INVASIVE BLOOD PRESSURE GAUGES

We, the manufacturer, herewith declare of Z12030205 - NON-INVASIVE BLOOD PRESSURE GAUGES
The Basic UDI-DI as referred in Part C of Annex VI:

Basic UDI-DI and Model:

Type	Basic UDI-DI	Mediblink Model	Combei Model
	69481584ARM02T4	M520	BP168A
	69481584ARM03T6	M510	BP880A
	69481584ARM04T8	M500; M540	BP866A; BP126A
Wrist	69481584WRIST02FQ	M505	BP606W

Risk class of the device in accordance with the rules set out in ANNEX VIII:

Class: IIa

Classification rule: EU 2017-745(MDR) ANNEX VIII Classification rules10

Products of Z12030205 - NON-INVASIVE BLOOD PRESSURE GAUGES mentioned above meet the regulations of
Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3
and Chapter III

Notified body involved:

Name: **TÜV Rheinland LGA Products GmbH**

Address: **Tillystraße 2, 90431, Nürnberg, Germany**

4 digit notified body
number:

C € 0197

Reference no. of Certificate No.: HZ 2111011-1

certificate: Issue date: 2024-5-30

Expiry date: 2029-5-29

following the procedure relating to the EC Declaration of Conformity set out in the REGULATION (EU) 2017/745
on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

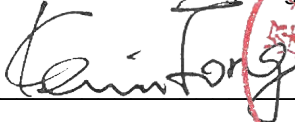
This Declaration of conformity is valid in connection with the release document for the respective batch of
produced devices.

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

Shenzhen Combei Technology Co., Ltd.

11-5B, No.105, Huanguan South Road, Dahe Community, Guanhu Street, Longhua District

Shenzhen 518110 Guangdong, P.R.China



Kevin Fong, Management Representative

June 11, 2024

Issued date

