

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

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

EUDAMED Single
Registration No.: CN-MF-000016047

Products: Products of class IIa:
Z12030205 - NON-INVASIVE BLOOD PRESSURE GAUGES

Authorized representative(s): MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-05-30

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 10922524-120

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Jason Pan

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This certificate can be validated on <https://www.certipedia.com>

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.



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