

EU DECLARATION OF CONFORMITY

Manufacturers Name: FAMIDOC Technology Co., Ltd

Manufacturers Address: Room 401, 501, 601, 901, Building 6, Zhongtang Tian'an Cyber Park, No. 89, Jinyuan Road,Zhongtang Town, Dongguan City, Guangdong Province, 523220, PR. China

SRN (Single Registration Number): CN-MF-000016603

Authorized Representative Name: Shanghai international Holding Corp. GmbH (Europe)

Authorized Representative Address: Eiffestrasse 80,20537 Hamburg,Germany

SRN (Single Registration Number): DE-AR-000000001

Basic UDI-DI: 697038963FDBPN8

Name of the Device (s): Upper Arm Blood Pressure Monitor

Product code and trade name: FDBP-A2,FDBP-A13

GMDN: 45617 Automatic-inflation electronic sphygmomanometer, portable, arm/wrist

EMDN: Z1203020302 - NON-INVASIVE BLOOD PRESSURE MONITORING INSTRUMENTS

Classification: MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters

Conformity assessment route: Class IIa Rule 10

Notified Body name: SGS Belgium NV

Notified Body Address: Noorderlaan 87,BE-2030 Antwerpen,Belgium
Phone : +32(0)3 545 48 60
Email : NB1639@sgs.com
Website : www.be.sgs.com

Notified Body Identification number: 1639

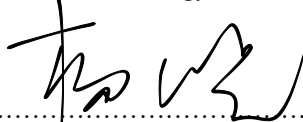
(EC) Certificate(s): CN23/00003635

Start of CE-marking: July 10.2023

Manufacturers Name: FAMIDOC Technology Co., Ltd uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745:
Class IIa: EC conformity declaration according to Annex IX Conformity assessment based on a quality management system and assessment of the technical documentation.

We herewith declare that the device is covered by the present declaration is in conformity with REGULATION (EU) 2017/745 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices and the EU declaration of conformity is issued under the sole responsibility of the manufacturer.
All supporting documentations are retained under the premises of the manufacturer.

Singed on behalf of
FAMIDOC Technology Co., Ltd



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HongGuang Yang
Management Representative

Place and date of issue:

Dongguan China, November 26, 2025

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