EU declaration of conformity

Manufacturer information:

Name: Shanghai Caremate Medical Device Co. Ltd

Registered trade name(or registered trade mark):Caremate

Address: Building 4,No.281 HongAn Road.Zhuijng Town Jinshan

SRN: CN-MF-000037470

Authorised representative information:

Name: MedPath GmbhH

Address : Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Product covered by the EU declaration of conformity:

Product name: Aneroid Sphygmomanometer

Model:CM-1621, CM-2621, CM-2021 ,CM-1329, CM-2243, CM-3003, CM-3410, CM-3001, CM-3412, CM-3411, CM-3413. CM-1013, BPM-AN-50, BPM-CH-50-HH, BPM-ST-SPL, CLOCK-Sphyg, BPM-AN-50-HH ,CM-BPM, CM-PBPM

Basic UDI-DI： 697132998200701VJ

EMDN Code:C9006

MDA Code:0203

MDS Code:1010

MDT Code Ⅰ:2001 MDT Code Ⅱ:2011 MDT Code Ⅲ:2002

Risk class: ClassI. According to the intended use and requirement in REGULATION (EU) 2017/745, the classification and definition are as followings: ANNEX VIII CLASSIFICATION RULES 4.1 Rule 1

All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

Applied Standard & Common Specification:EN ISO 81060-1.

Notified body:

Name: TÜV SÜD Product Service GmbH

Identification number: 0123

Conformity Assessment Procedure: Annex XI Part A

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.

Name: Fensen Zhu Function title:General manager

Signature: Mark.Zhu

Place: Shanghai

Date: 2023.11.25

Issue on behalf of Shanghai Caremate Medical Device Co. Ltd.