EU Declaration of Conformity

Manufacturer:

SRN:

European
Representative:
SRN:

EMDN Code: Z1203020302
Basic UDI-DI:

Intended purpose of device: The Wrist Blood Pressure Monitor is intended used to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Wrist.
Classification (MDR, Annex VIII): Class IIa, Rule 10.
Conformity Assessment Route: Annex IX Chapter I & III of Regulation (EU) 2017/745.

We herewith declare that the above-mentioned products meet the provisions of the MDR (EU) 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.
Applied standards, common specification, guidance:
EN ISO 13485:2016/A11:2021, EN ISO 15223-1:2021, EN ISO 20417:2021, EN ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015/A1:2021, IEC 80601-2-30:2018, ISO 81060-2:2018/+A1:2020, IEC 60601-1-11:2015+A1:2020, IEC 62304:2006+A1:2015, EN 62366-1-2015, EN 60601-1-6:2010+A1:2015, EN ISO 14971:2019/A11:2021, ISO/TR 24971:2020, ETSI EN 300 328 V2.2.2(2019-07), EN 62479:2010, EN 50663:2017, ETSI EN 301 489-1 V2.2.3(2019-11), ETSI EN 301 489-17 V3.2.4(2020-09), ASTM D4169-22, MEDDEV. 2.7.1 Rev.4.
Battery Directive 2006/66/EC, Battery Regulation (EU) 2023/1542，
Battery standard IEC/EN 60086-1:2021,IEC/EN 60086-2:2021,IEC/EN 60086-5:2021;

Notified Body: TÜV SÜD Product Service GmbH,
Ridlerstr. 65, 80339 München, Germany

NB Identification number: 0123
(EC) Certificate(s):
Expire date of the Certificate:
Start of CE Marking: