



EU DECLARATION OF CONFORMITY

Manufacturer: Huawei Device Co., Ltd.
No.2 of Xincheng Road, Songshan Lake Zone, Dongguan, 523808 Guangdong,
P.R.China
SRN: CN-MF-000022811

Authorized Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands
SRN: NL-AR-000000121

Product Name: Wrist Ambulatory Blood Pressure Monitor

Models: LCA-B29

Trade Name: HUAWEI WATCH D2

EMDN Code: Z12030203 - BLOOD PRESSURE MONITORING INSTRUMENTS
Z12050404 - BLOOD PRESSURE HOLTER RECORDERS

Basic UDI-DI: 694210319442319H6

Conformity Assessment Route: Chapter I and III of ANNEX IX of the Regulation (EU) 2017/745

Classification (MDR, Annex VIII): IIa / Rule 10, (MDR, ANNEX VIII)

Intended Purpose: This device is a digital self-monitor intended for use in measuring blood pressure, 24-hour ambulatory blood pressure, and pulse rate in adult population with wrist circumference ranging from 13.0 cm to 21.0 cm. Measurement results should not be used as the basis for diagnosis.

Applied Standards: See *Applied Standard List*

We herewith declare under sole responsibility that the above-mentioned products meet the transposition into national law, and the provisions of the following EU Council Regulations and Standards. All supporting documentation is retained at the premises of the manufacturer.

General applicable regulations: Medical Devices Regulation (EU) 2017/745.

Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Germany

NB Identification Number: 0197

(EU) Certificate(s): HZ 2042319-1

Expire Date of the Certificate(s): 2027-08-31

Start Date of CE Marking: 2025-07-15

Shen zhen 2025-07-15
Place, date /

Zhang qiang / PRRC
Name, position /