

EU Declaration of Conformity

Manufacturer: SHENGZHEN FINICARE CO., LTD.
201, No. 50, the 3rd Industrial Park, Houting Community, Shajing
Street, Bao'an District, 518104 Shenzhen, PEOPLE'S
REPUBLIC OF CHINA

SRN: CN-MF-000024364

European Representative: RIOMAVIX S.L.
Calle de Almansa 55, 1D, Madrid, 28039 Spain

SRN: ES-AR-000001202

Product Name: Infrared Thermometer

Model: FC-IR100
V0301010202

EMDN Code: See attachment 1.

Basic UDI-DI:

Intended purpose of device: The Upper Arm 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 upper arm. 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.

SHENGZHEN FINICARE CO., LTD. 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, guidances:

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, IEC 80601-2-30:2018, ISO 81060-2:2018, EN 1060-4:2004, IEC 60601-1-11:2015, IEC 62304:2006+A1:2015, EN 62366-1-2015+AC:2015, EN 60601-1-6:2010+A1:2015, EN ISO 14971:2019, 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 D4169-2016, MEDDEV. 2.7.1 Rev.4.

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

NB Identification number: 0123
(EC) Certificate(s): Not yet
Expire date of the Certificate: Not yet
Start of CE Marking: Not yet

Signature:
Name: Chao li
Position: General Manager
Place/date: Shenzhen City, 2022-07-24

Attachment 1. Product Basic UDI-DI information:

Models	Basic UDI-DI
FC-IR100	697152282IR001D3