

EU Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
Single Registration Number: JP-MF-000007213
Address: 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN
European Authorised Representative: OMRON HEALTHCARE EUROPE B.V.
Single Registration Number: NL-AR-000002683
Address: Wegalaan 73, 2132 JD Hoofddorp, THE NETHERLANDS
Product Category: Electronic Sphygmomanometers/Blood Pressure Monitors
Model (code): M3 Comfort AFib (HEM-7196-FLE)
Basic UDI-DI: 40156721143154
MDR Classification: Class IIa (MDR Annex VIII Rule 10)

We herewith declare, under our sole responsibility, that the above mentioned product meets the provisions of the following European Union Regulations, Council Directives and Standards. All supporting documentation is retained at the premises of the manufacturer and the European Authorized Representative.

This Declaration of Conformity is valid in connection with all the shipping inspection reports for the respective batch of produced devices.

General applicable regulations:	Medical Device Regulation (EU) 2017/745
Standards:	EN 60601-1:2006 +A1:2013 +A2:2021 EN ISO 10993-1:2020 EN 60601-1-2:2015 +A1:2021 EN ISO 10993-5:2009 EN 60601-1-6:2010 +A1:2015 +A2:2021 EN ISO 10993-10:2023 EN 60601-1-11:2015 +A1:2021 EN ISO 10993-23:2021 EN 62304:2006+A1:2015 EN ISO 13485:2016 EN 62366-1:2015 +A1:2020 EN ISO 13485:2016+A11:2021 EN 80369-5:2016 EN ISO 14971:2019+A11:2021 EN IEC 80601-2-30:2019 EN ISO 15223-1:2021 EN ISO 20417:2021 EN ISO 81060-2:2019 +A1:2020 +A2:2024
Notified Body:	TÜV Rheinland LGA Products GmbH
Address:	Tillystraße 2, 90431 Nürnberg, Germany
ID No:	Notified under number 0197 to the EC Commission
Certificate Registration No:	Annex IX: HZ 2102042-1

General applicable directives:	RoHS Directive 2011/65/EU, (EU)2015/863 and (EU)2017/2102
Product Category for RoHS:	Category 8 (Medical devices)
Standards:	EN IEC 63000:2018

Place / Date: Kyoto / February 26, 2025

Signature:

Name: 
Position: Takefumi Nakanishi
General Manager
Regulatory Affairs Department



Attachment to EU Declaration of Conformity No. OHQ(CS)-DoC(MDR)-3148296

Intended purpose of the model:

This device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population. The device can detect an irregular pulse suggestive of Atrial Fibrillation (AFib). Please note that the device is not intended to diagnose AFib.