No: OHQ(CS)-DoC(MDR)-3146959B

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):	M6 Comfort AFib (HEM-7380-E)
Basic UDI-DI:	4015672113975V
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 10993-10:2013
	EN 60601-1-11:2015 +A1:2021	EN ISO 13485:2016
	EN 62304:2006+A1:2015	EN ISO 14971:2019
	EN 62366-1:2015 +A1:2020	EN ISO 15223-1:2021
	EN IEC 80601-2-30:2019	EN ISO 20417:2021
		EN ISO 81060-2:2019+A1:2020
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 / April 5, 2024

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

Attachment to EU Declaration of Conformity No. OHQ(CS)-DoC(MDR)-3146959B

Intended purpose of the model:

This device is 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 Artial Fibrillation (AFib). Please note that the device is not intended to diagnose AFib. A diagnosis of AFib can only be confirmed by a physician with an Electrocardiogram (ECG). If the AFib symbol appears, consult with your physician.

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