OMRON

No: OHQ(CS)-DoC(MDR)-5674624

EC 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.
Address:	Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category:	Electronic Sphygmomanometers/Blood Pressure Monitors
Model (code):	X2 Smart (HEM-7143T2-ESL)
Basic UDI-DI:	4015672113054W
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 1041:2008+A1:2013	EN ISO 10993-1:2009/AC:2010
	EN 1060-1:1995+A2:2009	EN ISO 10993-5:2009
	EN 1060-3:1997+A2:2009	EN ISO 10993-10:2013
	EN 60601-1:2006+A1:2013	EN ISO 13485:2016
	EN 60601-1-2:2015	EN ISO 14971:2012
	EN 60601-1-6:2010+A1:2015	EN ISO 15223-1:2016
	EN 60601-1-11:2015	EN ISO 81060-2:2019+A1:2020
	EN 62304:2006+A1:2015	
	EN 62366-1:2015	
	EN IEC 80601-2-30:2019	
Notified Body:	TÜV Rheinland LGA Products GmbH	
Address:	Tillystrasse 2, 90431 Nuremberg, Germany	
ID No:	Notified under number 0197 to the EC Commission	
Certificate Registration No:	Annex IX : HZ 2102042-1	

General applicable directives:	Radio Equipment Directive 2014/53/EU	
Standards:	EN 300 328 V2.2.2	EN 301 489-1 V2.2.3
	EN 301 489-17 V3.2.4	EN 62479:2010
	EN IEC 62368-1:2020+A11:2020	

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 / September 13, 2021

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

All for Healthcare

OMRON HEALTHCARE Co., Ltd.
53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN