OMRON

No: OHQ(CS)-DoC(MDR)-9546009B

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:	Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category:	Accessory for Electronic Sphygmomanometers/Blood Pressure Monitors
Product Description:	Blood Pressure Monitor Cuff
Model (code):	GS CUFF2 L (HXA-GCFL-PBE)
Basic UDI-DI:	40156721115757
MDR Classification:	Class I (MDR Annex VIII Rule 1)

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 13485:2016
	EN 60601-1-6:2010+A1:2015	EN ISO 14971:2019
	EN 62366-1:2015	EN ISO 15223-1:2016
	EN IEC 80601-2-30:2019	EN ISO 81060-2:2019+A1:2020
	EN ISO 10993-1:2020	
	EN ISO 10993-5:2009	
	EN ISO 10993-10:2013	

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 / July 24, 2023

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

Attachment to EU Declaration of Conformity No. OHQ(CS)-DoC(MDR)-9546009B

Intended purpose of the model:

This product is an upper ann cuff for OMRON non-invasive blood pressure monitors.

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