No: OHQ(CS)-DoC(MDR)-9546045

EC Declaration of Conformity

Manufacturer:	OMRON HEALTHCARE Co., Ltd.
Single Registration Number:	pending issuance
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:	Accessory for Electronic Sphygmomanometers/Blood Pressure Monitors/Nebulizers
Product Description:	AC Adapter
Model:	HHP-CM01
UDI-DI:	04015672111677
MDR Classification:	Class I (MDR Annex VIII Rule 13)

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 60601-1:2006+A1:2013	EN ISO 14971:2012
	EN 60601-1-2:2015	EN ISO 15223-1:2016
	EN 60601-1-6:2010+A1:2015	
	EN 60601-1-11:2015	
	EN 62366:2008+A1:2015	

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 23, 2021

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department