OMRON

No: OHQ(CS)-DOC-100036E

EC Declaration of Conformity

Manufacturer:	OMRON HEALTHCARE Co., Ltd.
Address:	53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN
European Representative:	OMRON HEALTHCARE EUROPE B.V.
Address:	Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category:	Accessory for Electronic Sphygmomanometers/Blood Pressure Monitors
Product Description:	AC Adapter
Model (code) :	AC ADAPTER-S (HEM-ACW5-E)
Classification for MDD:	Class I (MDD Article 9 Annex IX Rule 1)
Product Category for RoHS:	Category 8 (Medical devices)

We herewith declare that the above mentioned product meets the provisions of the following European Committee Council Directives and Standards. All supporting documentation are retained at the premises of the manufacturer.
This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

Directives and Harmonized Standards

General applicable directives:	Relevant regulations and harmonized standards
93/42/EEC Medical Device Directive (MDD)	EN ISO 15223-1:2016 EN 1041:2008 EN 60601-1:2006+A1:2013 EN 60601-1-2:2015 EN 60601-1-6:2010 EN 60601-1-11:2010 EN 62366:2008 EN ISO 14971:2012 EN 80601-2-30:2010+A1:2015 EN13544-1:2007+A1:2009
2011/65/EU Restriction of Hazardous Substances (RoHS)	EN50581:2012

Place / Date: Kyoto / October 24, 2018

Signature:

T. Nakanishi

Name: Takefumi Nakanishi

Position: General Manager
Regulatory Affairs Department