

## 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  
Model: HEM-FL31  
Classification: Class I (MDD Article 9 Annex IX Rule 1)

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.

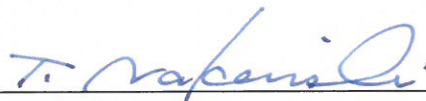
This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

### **Directives**

General applicable directives: 93/42/EEC Medical Device Directive(MDD)  
Standards: EN ISO 15223-1:2016  
EN 1041:2008  
EN 1060-1:1995+A2:2009  
EN 1060-3:1997+A2:2009  
EN 60601-1:2006+A1:2013  
EN 60601-1-6:2010  
EN 60601-1-11:2010  
EN 62366:2008  
EN ISO 10993-1:2009/AC:2010  
EN ISO 10993-5:2009  
EN ISO 10993-10:2013  
EN ISO 14971:2012  
EN 80601-2-30:2010+A1:2015  
EN ISO 81060-2:2014

Place / Date: Kyoto / October 4, 2018

Signature:



Name:

Takefumi Nakanishi

Position:

General Manager  
Regulatory Affairs Department