

EU Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
Address: 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN
European Authorised Representative: OMRON HEALTHCARE EUROPE B.V.
Address: Wegalaan 73, 2132 JD Hoofddorp, THE NETHERLANDS
Product Category: Electronic Sphygmomanometers/Blood Pressure Monitors
Model: X2 Smart+ (HEM-7146T2-ESL)

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 directive:	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

Place / Date: Kyoto / February 5, 2025

Signature:

Name: 
Position: Takefumi Nakanishi
General Manager
Regulatory Affairs Department