

No: OHQ(CS)-DoC(RED)-3146947

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 (code):

X7 Smart AFib (HEM-7380T1-EOSL)

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 / April 5, 2024

Signature:

Name:

Takefumi Nakanishi

Position:

General Manager

Regulatory Affairs Department