

EC Declaration of Conformity

Manufacturer: OMRON HEALTHCARE Co., Ltd.
Single Registration Number: JP-MF-000007213
Address: 53, Kunotsubo, Terado-cho, Muko, KYOTO, 617-0002 JAPAN
European Authorised Representative: OMRON HEALTHCARE EUROPE B.V.
Single Registration Number: NL-AR-000002683
Address: Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category: Body Composition Analyzers
Model (code): BF212 (HBF-212-EW)
Basic UDI-DI: 40156721070357
MDR Classification: Class I with Measuring Function (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 10993-1:2020
	EN 60601-1:2006+A1:2013
	EN ISO 10993-5:2009
	EN 60601-1-2:2015
	EN ISO 10993-10:2013
	EN 60601-1-6:2010+A1:2015
	EN ISO 13485:2016
	EN 60601-1-11:2010
	EN ISO 14971:2019
	EN 62304:2006
	EN ISO 15223-1:2016
	EN 62366-1:2015

Notified Body: TÜV Rheinland LGA Products GmbH
Address: Tillystrasse 2, 90431 Nuremberg, Germany
ID No: Notified under number 0197 to the EC Commission
Certificate Registration No: Annex IX: HZ 2102042-1

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 / February 28, 2023

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department



Attachment to EC Declaration of Conformity No. OHQ(CS)-DoC(MDR)-9063496

Intended purpose of the model:

It's intended to measure and display the following body composition parameters: body weight, body fat (in %) and Body Mass Index (BMI). The 4-sensor technology provides clinically validated body measurements. This unit is intended to be operated by adults who can understand this instruction manual.