

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): BF511 (HBF-511B-E)
Basic UDI-DI: 4015672104054U
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

Intended purpose of the model:

With this medical device you will be able to precisely measure the following body composition parameters and immediately interpret the results: • Body Fat (in %) • Visceral Fat (up to 30 levels) • Body Mass Index (BMI) • Skeletal Muscle (in %) In addition, the calculation of the Resting Metabolism Rate (in kcal) determines the daily calorie requirement and can act as a reference for weight reduction programme. The unique OMRON 8-sensor technology using both hands and feet provides one of the most accurate methods of entire body measurements. The OMRON Body Composition Monitor BF511 is suitable for children from 6 years onwards and adults and can weigh persons up to 150 kg. This unit is intended to be operated by adults who can understand this instruction manual.