

## 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): HBF-222T  
Basic UDI-DI: 497547949631PZ  
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 60601-1-11:2015      EN ISO 14971:2019 EN 62304:2006+A1:2015      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:	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

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 8, 2023

Signature:

Name:   
Position: Takefumi Nakanishi  
General Manager  
Regulatory Affairs Department



Attachment to EC Declaration of Conformity No. OHQ(CS)-DoC(MDR)-6601971

Intended purpose of the model:

Thank you for purchasing this OMRON Body Composition Monitor. This unit is intended for measuring and displaying the following body composition parameters. -- Body Weight -- Body Fat (in %) -- Visceral Fat (up to 30 levels) -- Skeletal Muscle (in %) -- Resting Metabolism (in kcal) -- BMI (Body Mass Index) Note: This device also calculates a Body Age for your reference. This Body Age is an indication only and it is not a medical relevant value. This unit is intended to be operated by adults who can understand this instruction manual. It is not for professional use in hospitals or other medical facilities, it is intended for home use only.