



No: OHQ(CS)-RAF-250187

EU 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: Wegalaan 73, 2132 JD Hoofddorp, THE NETHERLANDS
Product Category: Body Composition Analyzers
Model (code): VIVA (HBF-222T-EBK)
Basic UDI-DI: 4015672110904Y
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 Nürnberg, 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 / May 9, 2025

Signature:

Name: Takefumi Nakanishi
Position: General Manager
Regulatory Affairs Department

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Attachment to EU Declaration of Conformity No. OHQ(CS)-RAF-250187

Intended purpose of the model:

This unit is intended for measuring and displaying the following body composition parameters.

- Body Weight
- Visceral Fat (up to 30 levels)
- Resting Metabolism (in kcal)
- Body Fat (in%)
- Skeletal Muscle (in%)
- BMI (Body Mass Index)

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.