OMRON

No: OHQ(CS)-DOC-110193D

EC Declaration of Conformity

Manufacturer:	OMRON HEALTHCARE Co., Ltd.
Address:	53, Kunotsubo, Terado-cho, Muko, Kyoto 617-0002 JAPAN
European Representative:	OMRON HEALTHCARE EUROPE B.V.
Address:	Scorpius 33, 2132 LR Hoofddorp, The Netherlands
Product Category:	Body Composition Analyzers
Model Name(-code):	BF511(HBF-511B-E)
	BF511(HBF-511T-E)
Classification:	Class I with Measuring Function(MDD Annex IX Rule 12)

We herewith declare that the above mentioned product meets the provisions of the following European Committee Council Directives and Standards. All supporting documentation are retained under the premises of the manufacturer and the notified body.
This Declaration of Conformity is valid in connection with the shipping inspection reports for the respective batch of produced devices.

Directives

General applicable directives:	Medical Device Directive (MDD) 93/42/EEC
Standards:	EN980:2008 EN1041:2008 EN ISO10993-1:2009 EN ISO10993-5:2009 EN ISO10993-10:2009 EN ISO14971:2009 EN60601-1:1990+A1:1993+A2:1995 EN60601-1-2:2007 EN60601-1-4:1996+A1:1999 EN60601-1-6 :2004 EN62304:2006 EN62366:2008
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 V : DD 60100204 0001
Place / Date:	Kyoto / May 29, 2015
Signature:	
Name:	Norikazu Yasue
Position:	General Manager Customer Satisfaction Management Division