

# declaration of conformity



We, the manufacturer, declare in sole responsibility that the products mentioned below are in conformity with the respective regulations of the following directives.

<b>Category</b>	medical Body Composition Analyzer
<b>Product</b>	515
EC type-approval	D11-09-022
Accuracy class	III
Optional wireless transmission	x
Classification medical device	Class IIa
Conformity assessment procedure for medical devices	in accordance with Annex II excluding (4) of the Medical Devices Directive 93/42/EEC

## Directives:

- 2009/23/EC** Directive on non-automatic weighing instruments  
**93/42/EEC** Directive concerning medical devices  
**2011/65/EU** Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment  
**1999/5/EC** Directive on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity

**Manufacturer:** seca gmbh & co. kg  
Hammer Steindamm 9-25  
22089 Hamburg, Germany  
  
Made in Germany

**Notified Bodies:** 2009/23/EC: Hessische Eichdirektion  
Holzhofallee 3  
64283 Darmstadt, Germany  
93/42/EEC: TÜV SÜD Product Service GmbH  
Ridlerstrasse 65  
80339 Munich, Germany



This declaration of conformity is valid from the date of signature until a revised declaration of conformity is issued due to modification of the above-mentioned products.

Hamburg, 14 / 07 / 2014

**Frederik Vogel**  
CEO Development & Manufacturing

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## Annex

### Applied harmonised standards, national standards or other normative documents:

<b>EN 45501</b>	Metrological aspects of non-automatic weighing instruments
<b>EN 60601-1</b>	Medical electrical equipment - General requirements for basic safety and essential performance
<b>EN 60601-1-2</b>	Medical electrical equipment - Electromagnetic compatibility
<b>EN 62304</b>	Medical device software - Software life-cycle processes
<b>EN 300 328</b>	Electromagnetic compatibility and Radio spectrum Matters (ERM) - 2,4GHz
<b>EN 301 489-1</b>	Electromagnetic compatibility and Radio spectrum Matters (ERM) - Common technical requirements
<b>EN 301 489-17</b>	Electromagnetic compatibility and Radio spectrum Matters (ERM) - Specific conditions for Broadband Data Transmission Systems