# 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.

Category	Non-automatic electronic column scales
Product	285
EC type-approval	D10-09-017
Accuracy class	III
Optional wireless transmission	x
Classification medical device	Class I with measuring function
Conformity assessment procedure for medical devices	in accordance with Annex VI 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

The following additionally applies to products with wireless transmission:

Directive:

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: 93/42/EEC:

Hessische Eichdirektion TÜ

Holzhofallee 3

64283 Darmstadt, Germany

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:

**EN 45501** Metrological aspects of non-automatic weighing instruments

**EN 60601-1** Medical electrical equipment - General requirements for basic safety and essential

performance

EN 60601-1-2 Medical electrical equipment - Electromagnetic compatibility

## The following additionally applies to products with wireless transmission:

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

EN 300 328 Electromagnetic compatibility and Radio spectrum Matters (ERM) - 2,4GHz

EN 301 489-1 Electromagnetic compatibility and Radio spectrum Matters (ERM) - Common

technical requirements

EN 301 489-17 Electromagnetic compatibility and Radio spectrum Matters (ERM) - Specific

conditions for Broadband Data Transmission Systems