

# 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	Electronic measuring systems	
Products	264	274
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:

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

Made in Germany

**Notified Body:** 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:

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

### 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