

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 | medical Body Composition Analyzer |
| Product | 525 |
| 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:

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 3-25
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, 04 / 02 / 2016

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 |
| EN 60601-1-2 | Medical electrical equipment - Electromagnetic compatibility |
| EN 62304 | Medical device software - Software life-cycle processes |

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 |