



Product Service

EC Certificate

Product Quality Assurance

Directive 93/42/EEC on Medical Devices (MDD), Annex VI
(Devices in Class I with measuring function)

No. G3M 13 01 12163 023

Manufacturer:**seca****gmbh & co. kg.**

Hammer Steindamm 9-25

22089 Hamburg

GERMANY

**Product
Category(ies):**

**Medical scales, weighing systems and measuring
systems for assessing the health and nutritional
condition**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and test of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report no.:

713018027

Valid from:

2013-05-10

Valid until:

2018-05-09

**Date,** 2013-04-02
Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Facility(ies):

seca gmbh & co. kg.
Hammer Steindamm 9-25, 22089 Hamburg, GERMANY

declaration of conformity

seca

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 baby scales			
Products	384	385	834	835
EC type-approval	D06-09-024			
Accuracy class	III		III	
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

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

Made in China
Designed in Germany

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

declaration of conformity

seca

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