

# 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	seca emr flash
Product	101 from software version 1.2
Classification medical device	Class I
Conformity assessment procedure for medical devices	in accordance with Annex VII of the Medical Devices Directive 93/42/EEC

## Directive:

**93/42/EEC** Directive concerning medical devices

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

Made in 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, 02 / 07 / 2014

**Frederik Vogel**  
CEO Development & Manufacturing

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## Annex

Applied harmonised standards, national standards or other normative documents:

EN 62304                      Medical device software - Software life-cycle processes