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	ECG-Systems	
Product / Products	320	321
Classification as a 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	
With wireless transmission		x

Directive / Directives:

93/42/EEC Directive concerning medical devices

The following applies additionally to products with wireless transmission:

Directive:

2014/53/EU Directive on making available on the market of radio equipment

Manufacturer:
seca gmbh & co. kg
Hammer Steindamm 3-25
22089 Hamburg, Germany

Notified body / Notified bodies:
93/42/EEC:
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 München, Germany
Reference number: 0123

CE 0123

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, 07 / 03 / 2018

Frederik Vogel
CEO Development & Manufacturing

17-10-09-326b

declaration of conformity

Annex

Harmonised standards, national standards or other normative documents used:

EN 60601-1	:2006 + Cor.: 2010 + A1:2013	Medical electrical equipment - General requirements for basic safety and essential performance
EN 60601-1-2	:2007	Medical electrical equipment - Electromagnetic compatibility

The following additionally applies to products with wireless transmission:

Harmonised standards, national standards or other normative documents used:

EN 300 328	V2.1.1	Electromagnetic compatibility and Radio spectrum Matters (ERM) - 2,4GHz

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