

declaration of conformity



We, the manufacturer, declare in sole responsibility that the products mentioned below are in conformity with the respective regulations / directives of the following directives.

Basic UDI-DI	40120300000000000066R3		
Device Model Basic UDI-DI	ACDIS001eI		
Products	seca 495	seca 495 r	seca 496
Intended purpose	The display is intended to operate a compatible electronic platform scale. The interface box enables the power supply and the display to be connected to a compatible electronic platform scale. seca 495 r and seca 496 can also be connected to an external device for the transmission of measurement data. The display seca 495, seca 495 r or seca 496 must be combined with a compatible electronic platform scale to enable the measurement of weight.		
Classification as a medical device	I		
Conformity assessment procedure (EU) 2017/745	Art. 52 (7)		
With wireless transmission as an option			x

Regulations / Directives:

- (EU) 2017/745** Regulation on medical devices
2011/65/EU Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment

The following applies additionally to products with wireless transmission:

- 2014/53/EU** Directive relating to the making available on the market of radio equipment

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

Single Registration Number (SRN):
DE-MF-000005469

Made in Germany
Designed 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, 26 July 2024

Frederik Vogel
CEO Development & Manufacturing

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Annex

Applied standards and specifications:

EN 60601-1	2006 + Cor. :2010 + A1:2013
EN 60601-1-2	2015
EN 60601-1-11	2015
EN 62304	2006 + A1:2015

The following additionally applies to products with wireless transmission:

EN 300 328	V2.2.2 (2019-07)
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