

konformitätserklärung



Diese Konformitätserklärung ist gültig ab dem Datum der Unterzeichnung bis zur Ausstellung einer revidierten Konformitätserklärung aufgrund von Änderung der oben genannten Produkte.

Hamburg, 8. August 2023

A handwritten signature in black ink, appearing to read 'F. Vogel', is written over a horizontal line.

Frederik Vogel
CEO Development & Manufacturing

Anhang

Angewandte Normen und Spezifikationen:

EN 60601-1	:2013
EN 60601-1-2	:2016
EN 300 328	V2.2.2

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	40120300000000000001Q7	
Device Model Basic UDI-DI	MDBC001elmf	
Products	seca mBCA 554	seca mBCA 552
Intended purpose	The intended use of this product, resulting from the combination of the medical devices • mBCA scale: seca mBCA 552, seca mBCA 555, seca mBCA 554, • mBCA handrail: seca mBCA 550, seca mBCA 549, • height measurement rod: seca 257, seca 256, • cloud based software: seca analytics 125, and • server based configuration software: seca connect 103, is to assess the nutritional status, energy expenditure, and body water shifts by measuring weight, height, and bio-impedance data allowing for the determination of further body composition parameters. Additionally, changes in muscle and fat mass due to physical training are evaluated. The combination of the medical devices is used in hospitals, doctors' offices, ambulatory and stationary health care facilities, and fitness facilities.	
Classification as a medical device	IIa	
Conformity assessment procedure (EU) 2017/745	Annex IX	
Certificate (EU) 2017/745	G10 012163 0088	

Regulations / Directives:

(EU) 2017/745	Regulation on medical devices
2014/53/EU	Directive relating to the making available on the market of radio equipment
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 3-25 22089 Hamburg, Germany	Single Registration Number (SRN): DE-MF-000005469
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Made in Germany
Designed in Germany

Notified body / Notified bodies:	(EU) 2017/745: TÜV SÜD Product Service GmbH Ridlerstrasse 65 80339 München, Germany Reference number: 0123
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declaration of conformity



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, 08 August 2023

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Frederik Vogel
CEO Development & Manufacturing

declaration of conformity



Annex

Applied standards and specifications:

EN 60601-1	:2013
EN 60601-1-2	:2016
EN 300 328	V2.2.2