

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	40120300000000000069R9	
Device Model Basic UDI-DI	ACMA006me	
Products	seca 446	seca 448
Intended purpose	The guardrail is intended to prevent the clinical staff from accidentally pushing a patient's wheelchair, stretcher or bed over the side edge of a compatible scale to enable a safe weighing of patients sitting in a wheelchair or lying in a bed or on a stretcher.	
Classification as a medical device	I	
Conformity assessment procedure (EU) 2017/745	Art. 52 (7)	

Regulations / Directives:

(EU) 2017/745 Regulation on medical devices

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 ISO 20417	2021
EN ISO 15223-1	2021