Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 012163 0089 Rev. 01

Manufacturer:

seca gmbh & co. kg
Hammer Steindamm 3-25
22089 Hamburg
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 012163 0089 Rev. 01

Report No.:	713176915
Preceding Certificate No.:	G11 012163 0089 Rev. 00
Valid from:	2021-05-05
Valid until:	2025-08-11
Date of Initial Issuance:	2020-08-12

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-05-05

Digitally signed by Iarovoi Petru
Date: 2023.11.08 13:41:26 EET
Reason: MoldSign Signature
Location: Moldova

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 012163 0089 Rev. 01

Classification:	I
Device Group:	V0399 - MEASUREMENT DEVICES - OTHERS
Device Properties:	MDS 1010 - Devices with a measuring function
The validity of this certificate depends on conditions and/or is limited to the following:	-/-

Revision History:

Rev.	Dated	Report
00	2020-08-12	713176915

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

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	Mechanical measuring systems									
Products	201	203	213	216	217	218	220	222	223	224
Classification medical device	Class I with measuring function									
Conformity assessment procedure for medical de-	in accordance with Annex VI of the Medical Devices Directive 93/42/EEC									

Directive:

93/42/EEC Directive concerning medical devices

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

Made in China
Designed in Germany

Notified Body:
93/42/EEC:
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 Munich, Germany

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, 15 / 04 / 2018

Frederik Vogel
CEO Development & Manufacturing

17-10-09-297e