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. 00

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.

Report No.: 713176915

Valid from: 2020-08-12
Valid until: 2025-08-11

Issue date: 2020-08-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	I
Device Group:	MDA 0204 - Other active non-implantable devices for monitoring and/or diagnosis (e.g. Devices for lung function diagnosis, Devices for measurement of hearing capability, EEG, EMG, Sleep diagnosis, Medical scales, Biofeedback/Neurofeedback, Audiometers)
Device Properties:	MDT 2010 - Devices manufactured using electronic components including communication devices MDT 2011 - Devices which require packaging, including labelling
The validity of this certificate depends on conditions and/or is limited to the following:	-/-

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