ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 IIa and Class IIb Devices)

No. G10 005260 0004 Rev. 02

Manufacturer:

Sentec AG
Ringstr. 39
4106 THERWIL
SWITZERLAND

SRN Manufacturer - CH-MF-000008058

Authorized Representative:

SenTec GmbH
Carl-Hopp-Str. 19A, 18069 Rostock, 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.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 005260 0004 Rev. 02

Report No.: 713340401

Preceding Certificate No.: G10 005260 0004 Rev. 01

Valid from: 2024-09-04
Valid until: 2026-08-08

Date of Initial Issuance: 2021-08-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-04

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

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No. G10 005260 0004 Rev. 02

Classification:	Class IIb
Device Group:	Z12030204 - GASEOUS EXCHANGE MONITORING INSTRUMENTS
Intended Purpose:	The Sentec Digital Monitoring System – consisting of monitors and sensors – is indicated for noninvasive patient monitoring of oxygenation and ventilation
Classification:	Class IIb
Device Group:	Z1203020482 - GASEOUS EXCHANGE MONITORING INSTRUMENTS - SOFTWARE ACCESSORIES
Intended Purpose:	V-STATS™ is an optional PC-based software, which is intended for use with Sentec monitors when remote monitoring and/ or trend reporting and statistical analysis of data measured by the monitor is required. V-STATS™ is not intended to provide diagnosis; it is intended to supplement and not to replace any part of the monitoring procedures
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description
00	2021-08-09	713194686	-
01	2022-06-13	713217607	-
02	2024-09-04	713340401	Supplemented: Change to the approved type(s)/device(s)

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