ZERTIFIKAT ◆ 认证证书 ◆ CERTIFICATE ◆ 認証書 ◆ CERTIFICATO ◆ 인증서 ◆ CERTIFICADO

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

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 005260 0005 Rev. 01

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 quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective 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.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III (excluding custom-made implantable devices) or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 005260 0005 Rev. 01

Report No.: 713387314
Preceding Certificate No.: G15 005260 0005 Rev. 00

Valid from: 2026-08-09
Valid until: 2031-08-08
Date of Initial Issuance: 2026-08-09

Issue date: 2026-08-05

Christoph Dicks
Head of Certification/Notified Body

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Certificate No. G15 005260 0005 Rev. 01

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
Classification:	Class IIa
Device Group:	MDA 0202 - Active non-implantable imaging devices utilising non-ionizing radiation
The validity of this certificate depends on conditions and/or is limited to the following:	- none -

Revision History:

Rev.	Dated	Report	Description	
00	2026-08-09	713404148	Renewal of certificate	
01	2026-08-09	713387314	Supplemented: Other	Voluntary Transfer of MDR Certificate

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