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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 015735 0033 Rev. 01

Manufacturer: **Sedatelec**
Chemin des Mûriers
69540 Irigny
FRANCE

SRN Manufacturer - FR-MF-000020946

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 015735 0033 Rev. 01

Report No.:	713409734
Preceding Certificate No.:	G15 015735 0033 Rev. 00
Valid from:	2026-06-17
Valid until:	2030-06-03
Date of Initial Issuance:	2025-06-04

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2026-06-17

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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Classification:	Class IIa
Device Group:	MDN 1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care
Classification:	Class IIa
Device Group:	MDA 0302 - Active non-implantable devices utilising non-ionizing radiation
Classification:	Class IIa
Device Group:	MDA 0305 - Active non-implantable devices for stimulation or inhibition
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report	Description
00	2025-06-04	713278454	Initial issuance
01	2026-06-17	713409734	Supplemented: Device(s)/group of device(s) added

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