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

C E R T I F I C A T E

No. QS6 015735 0029 Rev. 03

Certificate Holder: **Sedatelec**
Chemin des Mûriers
69540 Irigny
FRANCE

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Sterile Medical Needles, Medical Lasers, Skin, Nerves and Muscles Stimulators for Therapeutical Applications**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 015735 0029 Rev. 03
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F001337**
Report No.: **713415147**
Effective Date: **2026-12-06**
Expiry Date: **2029-12-05**

Date of Issue: 2026-11-16

(Sofia Epshtein Elbrus)

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MDSAP
Medical Device Single Audit Program

TÜV SÜD

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No. QS6 015735 0029 Rev. 03

Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Canada
- Medical Device Regulations – Part 1- SOR 98/282

Japan
- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **Sedatelec**
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