



America

CERTIFICATE

No. QS6 015735 0029 Rev. 00

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, 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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: 26-603-1462

Effective Date: 2020-08-07

Expiry Date: 2021-05-03

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Date of Issue: 2020-08-27

(Tina Israel)
Manager, US Certification Body,
Medical and Health Services

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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

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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Facility Scopes:

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