



America

CERTIFICATE

No. QS6 058654 0016 Rev. 04

Certificate Holder:

SPINEVISION SAS

3 Rue de la Renaissance
92160 Antony
FRANCE

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Sterile and Non-Sterile Prostheses, Spinal Fixation or Stabilization Systems and Spinal Fusion Systems as well as related Instruments

Standard(s):

ISO 13485:2016

Regulatory Authority(ies):

**Australia TGA, Brazil ANVISA, 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6 058654 0016 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:QS6_058654_0016_Rev.04)

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID:

F001354

Report No.:

713343623

Effective Date:

2024-11-21

Expiry Date:

2027-02-25

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(Renee Walker)
Director, US Certification Body, MHS

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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

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

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):

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Facility Scopes:

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