



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Implantable Class IIb Devices and Class III Devices)

No. G12 058654 0019 Rev. 01

Manufacturer:

SPINEVISION SAS

3 Rue de la Renaissance
92160 Antony
FRANCE

SRN Manufacturer - FR-MF-000001549

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. In order to place the devices on the market with CE-marking, an EU Technical Documentation Assessment Certificate pursuant to Annex IX chapter II is necessary in addition to this EU Quality Management System Certificate. 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:G12 058654 0019 Rev. 01

Report No.: 713351914

Preceding Certificate No.: G12 058654 0019 Rev. 00

Valid from: 2025-02-04

Valid until: 2029-09-08

Date of Initial Issuance: 2024-09-09

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-04



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No. G12 058654 0019 Rev. 01

Classification: Class III
Device Group: P090701 - SPINAL FUSION SYSTEMS
Intended Purpose: ./.

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2024-09-09	713282548	Initial issuance
01	2025-02-04	713351914	Amended: Change of certificate holder's data