ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 058654 0023 Rev. 01

Manufacturer:

SPINEVISION SAS
3 Rue de la Renaissance
92160 Antony
FRANCE

SRN Manufacturer - FR-MF-000001549

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 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 058654 0023 Rev. 01

Report No.: 713294232_CN
Preceding Certificate No.: G15 058654 0023 Rev. 00

Valid from: 2025-05-21
Valid until: 2029-09-08
Date of Initial Issuance: 2025-04-10

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-05-21

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Certificate No. G15 058654 0023 Rev. 01

Classification:	Class IIa
Device Group:	MDN 1208 - Non-active non-implantable instruments
Classification:	Class IIb
Device Group:	P090703 - IMPLANTABLE VERTEBRAL STABILISATION OR FIXATION SYSTEMS
Intended Purpose:	The instrumentation is designed for correction and surgical stabilization of the spine during development of solid bone fusion. It is recommended to remove the device as soon as effective solid bone fusion has been achieved.
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Rev.	Dated	Report	Description
00	2025-04-10	713330731	Initial issuance
01	2025-05-21	713294232_CN	Supplemented: Device(s)/group of device(s) added

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