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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-MDR-099

Product Service

# EU Technical Documentation Assessment Certificate (MDR)

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

## No. G70 058654 0017 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 drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation 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 technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result. Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapters I and III is necessary in addition to this EU Technical Documentation Assessment 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:G70 058654 0017 Rev. 01

| | |
|---|---|
| **Report No.:** | 713351866 |
| **Preceding Certificate No.:** | G70 058654 0017 Rev. 00 |
| **Valid from:** | 2025-01-16 |
| **Valid until:** | 2029-08-06 |
| **Date of Initial Issuance:** | 2024-08-07 |

Christoph Dicks
Head of Certification/Notified Body

**Issue date:** 2025-01-16


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**Classification:** Class III
**Device Group:** P090701 - SPINAL FUSION SYSTEMS
**Basic UDI-DI:** 3663136TLIFCAGE5E
**Intended Purpose:** The Hexanium® TLIF (Transforaminal Lumbar Interbody Fusion) system is intended as intervertebral body fusion device of the lumbar spine (L2-S1). It is intended to be implanted via a transforaminal approach to give a primary stability of the anterior column (with or without restoring disc height) until fusion occurs. Hexanium® TLIF intervertebral body fusion device must be combined with an appropriate posterior lumbar fixation device, e.g. the SPINEVISION®, Plus®, Ulis® or Lumis ® .
**Device(s):** Hexanium® TLIF

**List of variants for Basic UDI-DI : 3663136TLIFCAGE5E**

| Item count | Article / Model number | Article name/description |
|---|---|---|
| 1 | TL3-CM07 | Ti TLIF cage Medium H07 mm |
| 2 | TL3-CM08 | Ti TLIF cage Medium H08 mm |
| 3 | TL3-CM09 | Ti TLIF cage Medium H09 mm |
| 4 | TL3-CM10 | Ti TLIF cage Medium H10 mm |
| 5 | TL3-CM11 | Ti TLIF cage Medium H11 mm |
| 6 | TL3-CM12 | Ti TLIF cage Medium H12 mm |
| 7 | TL3-CM13 | Ti TLIF cage Medium H13 mm |
| 8 | TL3-CM14 | Ti TLIF cage Medium H14 mm |
| 9 | TL3-CM15 | Ti TLIF cage Medium H15 mm |
| 10 | TL3-CM16 | Ti TLIF cage Medium H16 mm |
| 11 | TL3-CS07 | Ti TLIF cage Small H07 mm |
| 12 | TL3-CS08 | Ti TLIF cage Small H08 mm |
| 13 | TL3-CS09 | Ti TLIF cage Small H09 mm |
| 14 | TL3-CS10 | Ti TLIF cage Small H10 mm |
| 15 | TL3-CS11 | Ti TLIF cage Small H11 mm |
| 16 | TL3-CS12 | Ti TLIF cage Small H12 mm |
| 17 | TL3-CS13 | Ti TLIF cage Small H13 mm |
| 18 | TL3-CS14 | Ti TLIF cage Small H14 mm |
| 19 | TL3-CS15 | Ti TLIF cage Small H15 mm |
| 20 | TL3-CS16 | Ti TLIF cage Small H16 mm |
| 21 | TL3-SCS07 | Ti Straight TLIF Cage Small H07 mm |
| 22 | TL3-SCS08 | Ti Straight TLIF Cage Small H08 mm |


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| | | |
|---|---|---|
| 23 | TL3-SCS09 | Ti Straight TLIF Cage Small H09 mm |
| 24 | TL3-SCS10 | Ti Straight TLIF Cage Small H10 mm |
| 25 | TL3-SCS11 | Ti Straight TLIF Cage Small H11 mm |
| 26 | TL3-SCS12 | Ti Straight TLIF Cage Small H12 mm |
| 27 | TL3-SCS13 | Ti Straight TLIF Cage Small H13 mm |
| 28 | TL3-SCS14 | Ti Straight TLIF Cage Small H14 mm |
| 29 | TL3-SCS15 | Ti Straight TLIF Cage Small H15 mm |
| 30 | TL3-SCS16 | Ti Straight TLIF Cage Small H16 mm |
| 31 | TL3-SCM07 | Ti Straight TLIF Cage Medium H07 mm |
| 32 | TL3-SCM08 | Ti Straight TLIF Cage Medium H08 mm |
| 33 | TL3-SCM09 | Ti Straight TLIF Cage Medium H09 mm |
| 34 | TL3-SCM10 | Ti Straight TLIF Cage Medium H10 mm |
| 35 | TL3-SCM11 | Ti Straight TLIF Cage Medium H11 mm |
| 36 | TL3-SCM12 | Ti Straight TLIF Cage Medium H12 mm |
| 37 | TL3-SCM13 | Ti Straight TLIF Cage Medium H13 mm |
| 38 | TL3-SCM14 | Ti Straight TLIF Cage Medium H14 mm |
| 39 | TL3-SCM15 | Ti Straight TLIF Cage Medium H15 mm |
| 40 | TL3-SCM16 | Ti Straight TLIF Cage Medium H16 mm |


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

**Revision History:**

| Rev. | Dated | Report | Description |
|---|---|---|---|
| 00 | 2024-08-07 | 0713270864 | Initial issuance |
| 01 | 2025-01-16 | 713351866 | Amended: Change of certificate holder's data |


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