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 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 0018 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 0018 Rev. 01

Report No.:	713351866
Preceding Certificate No.:	G70 058654 0018 Rev. 00
Valid from:	2025-01-15
Valid until:	2029-06-24
Date of Initial Issuance:	2024-06-25

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-01-15

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 0018 Rev. 01

Classification: Class III
Device Group: P090701 - SPINAL FUSION SYSTEMS
Basic UDI-DI: 3663136ACIFCAGEM9
Intended Purpose: The Hexanium® ACIF (Anterior Cervical Interbody Fusion) system is intended as a standalone intervertebral body fusion device of the cervical spine (C3-C7). It is intended to be implanted via an anterior approach to give a primary stability of the cervical column (with or without restoring disc height) until fusion occurs.
Device(s): Hexanium® ACIF

Item count #1-48 covers in total 48 Hexanium® ACIF device variants listed at the end of this certificate.

Classification: Class III
Device Group: P090701 - SPINAL FUSION SYSTEMS
Basic UDI-DI: 3663136ACIFSCRWT8
Intended Purpose: The Hexanium® ACIF (Anterior Cervical Interbody Fusion) system is intended as a standalone intervertebral body fusion device of the cervical spine (C3-C7). It is intended to be implanted via an anterior approach to give a primary stability of the cervical column (with or without restoring disc height) until fusion occurs.
Device(s): Hexanium® ACIF

Item count #49-56 covers in total 8 Hexanium® ACIF Self Drilling Screw device variants listed ate.at the end of this certificate

List of variants for Basic UDI-DI 3663136ACIFCAGEM9:

Item count	Article/Model number	Article name/description
1	AC2-CSL05C	Convex Ti SA Cervical Cage - Large H05 mm
2	AC2-CSL05L	Lordotic Ti SA Cervical Cage - Large H05 mm
3	AC2-CSL06C	Convex Ti SA Cervical Cage - Large H06 mm
4	AC2-CSL06L	Lordotic Ti SA Cervical Cage - Large H06 mm
5	AC2-CSL07C	Convex Ti SA Cervical Cage - Large H07 mm

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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

TÜV SÜD 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 0018 Rev. 01

6	AC2-CSL07L	Lordotic Ti SA Cervical Cage - Large H07 mm
7	AC2-CSL08C	Convex Ti SA Cervical Cage - Large H08 mm
8	AC2-CSL08L	Lordotic Ti SA Cervical Cage - Large H08 mm
9	AC2-CSL09C	Convex Ti SA Cervical Cage - Large H09 mm
10	AC2-CSL09L	Lordotic Ti SA Cervical Cage - Large H09 mm
11	AC2-CSL10C	Convex Ti SA Cervical Cage - Large H10 mm
12	AC2-CSL10L	Lordotic Ti SA Cervical Cage - Large H10 mm
13	AC2-CSL11C	Convex Ti SA Cervical Cage - Large H11 mm
14	AC2-CSL11L	Lordotic Ti SA Cervical Cage - Large H11 mm
15	AC2-CSL12C	Convex Ti SA Cervical Cage - Large H12 mm
16	AC2-CSL12L	Lordotic Ti SA Cervical Cage - Large H12 mm
17	AC2-CSM05C	Convex Ti SA Cervical Cage - Medium H05 mm
18	AC2-CSM05L	Lordotic Ti SA Cervical Cage - Medium H05 mm
19	AC2-CSM06C	Convex Ti SA Cervical Cage - Medium H06 mm
20	AC2-CSM06L	Lordotic Ti SA Cervical Cage - Medium H06 mm
21	AC2-CSM07C	Convex Ti SA Cervical Cage - Medium H07 mm
22	AC2-CSM07L	Lordotic Ti SA Cervical Cage - Medium H07 mm
23	AC2-CSM08C	Convex Ti SA Cervical Cage - Medium H08 mm
24	AC2-CSM08L	Lordotic Ti SA Cervical Cage - Medium H08 mm
25	AC2-CSM09C	Convex Ti SA Cervical Cage - Medium H09 mm
26	AC2-CSM09L	Lordotic Ti SA Cervical Cage - Medium H09 mm
27	AC2-CSM10C	Convex Ti SA Cervical Cage - Medium H10 mm

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 0018 Rev. 01

28	AC2-CSM10L	Lordotic Ti SA Cervical Cage - Medium H10 mm
29	AC2-CSM11C	Convex Ti SA Cervical Cage - Medium H11 mm
30	AC2-CSM11L	Lordotic Ti SA Cervical Cage - Medium H11 mm
31	AC2-CSM12C	Convex Ti SA Cervical Cage - Medium H12 mm
32	AC2-CSM12L	Lordotic Ti SA Cervical Cage - Medium H12 mm
33	AC2-CSS05C	Convex Ti SA Cervical Cage - Small H05 mm
34	AC2-CSS05L	Lordotic Ti SA Cervical Cage - Small H05 mm
35	AC2-CSS06C	Convex Ti SA Cervical Cage - Small H06 mm
36	AC2-CSS06L	Lordotic Ti SA Cervical Cage - Small H06 mm
37	AC2-CSS07C	Convex Ti SA Cervical Cage - Small H07 mm
38	AC2-CSS07L	Lordotic Ti SA Cervical Cage - Small H07 mm
39	AC2-CSS08C	Convex Ti SA Cervical Cage - Small H08 mm
40	AC2-CSS08L	Lordotic Ti SA Cervical Cage - Small H08 mm
41	AC2-CSS09C	Convex Ti SA Cervical Cage - Small H09 mm
42	AC2-CSS09L	Lordotic Ti SA Cervical Cage - Small H09 mm
43	AC2-CSS10C	Convex Ti SA Cervical Cage - Small H10 mm
44	AC2-CSS10L	Lordotic Ti SA Cervical Cage - Small H10mm
45	AC2-CSS11C	Convex Ti SA Cervical Cage - Small H11 mm
46	AC2-CSS11L	Lordotic Ti SA Cervical Cage - Small H11 mm
47	AC2-CSS12C	Convex Ti SA Cervical Cage - Small H12 mm
48	AC2-CSS12L	Lordotic Ti SA Cervical Cage - Small H12 mm

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 0018 Rev. 01

List of variants for Basic UDI-DI 3663136ACIFSCRWT8:

Item count	Article/Model number	Article name/description
49	AC2-SD3510S	Self Drilling Screws - Ø3.5 mm L10mm
50	AC2-SD3512S	Self Drilling Screws - Ø3.5 mm L12mm
51	AC2-SD3514S	Self Drilling Screws - Ø3.5 mm L14mm
52	AC2-SD3516S	Self Drilling Screws - Ø3.5 mm L16mm
53	AC2-SD3810S	Self Drilling Screws - Ø3.8 mm L10mm
54	AC2-SD3812S	Self Drilling Screws - Ø3.8 mm L12mm
55	AC2-SD3814S	Self Drilling Screws - Ø3.8 mm L14mm
56	AC2-SD3816S	Self Drilling Screws - Ø3.8 mm L16mm

-

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
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 0018 Rev. 01

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

Revision History:

Rev.	Dated	Report	Description
00	2024-06-25	713277747	Initial issuance
01	2025-01-15	713351866	Amended: Change of certificate holder's data

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany