

Deutsche Akkreditierungsstelle German Accreditation Body

Annex to accreditation certificate D-PL-13415-02-00 according to DIN EN ISO/IEC 17025:2018

Effective from: 09.07.2026

Date of issue: 09.07.2026

This annex to the certificate forms part of accreditation certificate D-PL-13415-02-00.

Holder of the Certificate:

**SpineServ GmbH & Co. KG
Söflinger Straße 100, 89077 Ulm**

With the location:

**SpineServ GmbH & Co. KG
Söflinger Straße 100, 89077 Ulm**

The testing laboratory fulfills the requirements according to DIN EN ISO/IEC 17025:2018 to perform the conformity assessment activities listed in this annex. The testing laboratory complies with additional legal and normative requirements, including those in relevant sectoral programs, where applicable, provided these are explicitly confirmed below.

The requirements for the management system in DIN EN ISO/IEC 17025 are written in a language relevant for testing laboratories and are generally in accordance with the principles of DIN EN ISO 9001.

Physical and Chemical Testing of Medical Devices

outside of a recognition according to § 18 Medical Devices Implementation Act

This certificate annex is only valid together with the certificate issued in writing and reflects the status at the time of issue. The current status of the valid and monitored accreditation can be found in the database of accredited bodies of the German Accreditation Body (www.dakks.de)

Abbreviations used: see last page

Annex to Accreditation Certificate D-PL-13415-02-00

Testing area	Device category	Test method / Test type	Standard method of testing
Chemical Testing	hip joint replacement - modular implant interfaces	determination of requirements - fretting corrosion testing	ASTM F1875
	bone screws	- corrosion testing	ASTM F897
	infusion and injection systems - needle tubing	determination of requirements - corrosion resistance	DIN EN ISO 9626
Physical Testing	dental implants	determination of properties - fatigue testing of endosseous dental implants - static torsion test	DIN EN ISO 14801 ISO/TS 13498
	partial and total hip joint replacement - head fixation - acetabular shells - taper connections of modular prostheses - metallic stemmed femoral prostheses - modular acetabular devices - stemmed femoral components - head and neck region of stemmed femoral components - total hip replacement	determination of properties - resistance to torque - sphericity - deformation test - fatigue testing - determination of the disassembly forces - compression test - fatigue testing - disassembly tests - endurance properties with torsion - endurance properties - impingement test	ISO 7206-13 ISO 7206-2 ASTM F2033 ISO 7206-12 ASTM F3090 ASTM F2345 ASTM F2009 ISO 7206-10 ASTM F2068 ASTM F1820 ISO 7206-4 ISO 7206-6 ASTM F2582

Testing area	Device category	Test method / Test type	Standard method of testing
		- wear test - frictional torque	ISO 14242-1 ASTM F3446
	infusion and injection accessories - needle-based injection systems - peak flow meter - connectors - needle tubing - syringes	performance requirement - dose accuracy - flow rate - leakage tests, resistance to separation tests, torsion and tensile tests, strength tests - stress cracking - strength and stiffness tests - pull-off and torsion tests - glide force tests - leakage tests - strength tests - determination of the dead space	DIN EN ISO 11608-1 DIN EN ISO 23747 DIN EN ISO 7886-1 DIN EN ISO 80369-20 applicable: DIN EN ISO 80369-1 DIN EN ISO 80369-3 DIN EN 80369-5 DIN EN ISO 80369-6 DIN EN ISO 80369-7 DIN 13276 DIN EN ISO 9626 DIN EN ISO 7886-1
	- prefilled syringes	- pull-off and torsion tests - glide force tests - leakage tests - strength tests - determination of the dead space	DIN EN ISO 11040-4 ISO 11040-6 ISO 11040-8
	- infusion sets	- leakage tests - pull-off tests	DIN EN ISO 8536-4
	Catheters - catheters and accessory devices	determination of properties - kink and strength tests - corrosion tests	DIN EN ISO 20697

Testing area	Device category	Test method / Test type	Standard method of testing
		- subatmospheric pressure tests - flow rate tests - leakage tests	
	knee replacement - tibial tray - total knee joint replacement	determination of properties - fatigue testing - determination of total knee replacement constraint - mobile bearing rotational stops - dislocation - resistance to dynamic disassociation - fatigue testing under high flexion - fatigue testing of unicondylar tibial trays - fatigue testing femoral component - disassembly tests - wear testing	ISO 14879-1 ASTM F1800 ASTM F1223 ASTM F2722 ASTM F2724 ASTM F2723 ASTM F2777 ASTM F3140 ASTM F3210 ASTM F1814 ISO 14243-1 ISO 14243-3 ISO 14243-5 applicable: ISO 14243-2 ASTM F2083
	ankle replacement - total ankle joint replacement	determination of properties - wear testing	ISO 22622
	osteosynthesis implants - bone plates - small bone plates - bone screws - intramedullary nails - external fixators - angled fracture	determination of properties - static and dynamic testing - static and dynamic testing - static testing - static and dynamic testing - static and dynamic testing - static and dynamic testing	ASTM F382 S-09 (WK52025-2017) ASTM F543 ASTM F1264 ASTM F1541 ASTM F384

Testing area	Device category	Test method / Test type	Standard method of testing
	fixation devices		
	- absorbable plates and screws	- mechanical testing	ASTM F2502
	- wires and cables	- static testing	ASTM F2180
	shoulder replacement	determination of properties	
	- glenoid component	- glenoid loosening or disassociation	ASTM F2028
	sterile barrier and packaging systems	requirements and test methods	DIN EN ISO 11607-1
	- glenoid component	- seal strength	ASTM F88/F88M
	materials	determination of properties	
	- plastics	- shear strength using punch tool	ASTM D732
	- bone cement	- fatigue testing	ASTM F2118
	- UHMWPE	- accelerated aging	ASTM F2003
	- coatings	- adhesion forces	ISO 13779-4 ASTM F1147
		- shear and bending strength	ASTM F1160
		- shear strength	ASTM F1044
	spinal Implants	determination of properties	
	- motion preserving implants	- fatigue testing with anterior support	ISO 12189
		- static, dynamic, and wear assessment of extra-discal spinal constructs	ASTM F2624
	- internal fixation devices	- static and dynamic testing in a vertebrectomy model	ASTM F1717 ASTM F2706
		- static and fatigue properties of subassemblies	ASTM F1798
		- static and dynamic testing of single components	ASTM F2193
	- fusion implants	- static and dynamic testing	ASTM F2077
		- static expulsion testing	S-01
		- static luxation testing	S-02
		- subsidence testing	ASTM F2267

Testing area	Device category	Test method / Test type	Standard method of testing
	- surface-coated intervertebral fusion devices	- impaction test	S-07 (ASTM F1044) (ASTM F1147) (ISO 14242-2)
	- spinal artificial discs	- static and dynamic testing	ASTM F2346
		- static expulsion testing	S-01
		- static luxation testing	S-02
	- spinal artificial discs	- wear testing	ISO 18192-1 ASTM F2423
		- determination of the tribological characteristics	ISO 14242-2 ASTM F1714 ASTM F2025

Set of rules

ISO 7206-2: 2011	Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials
ISO 7206-4: 2010-06	Implants for surgery — Partial and total hip joint prostheses — Part 4: Determination of endurance properties and performance of stemmed femoral components
ISO 7206-6: 2013-11	Implants for surgery — Partial and total hip joint prostheses — Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components
ISO 7206-10: 2018-08	Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads
ISO 7206-12: 2016-10	Implants for surgery — Partial and total hip joint prostheses — Part 12: Deformation test method for acetabular shells
ISO 7206-13: 2016-07	Implants for surgery — Partial and total hip joint prostheses — Part 13: Determination of resistance to torque of head fixation of stemmed femoral components
DIN EN ISO 7886-1: 2020-11	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use (ISO 7886-1:2017)
DIN EN ISO 8536-4:2020-05	Infusionsgeräte zur medizinischen Verwendung - Teil 4: Infusionsgeräte für Schwerkraftinfusionen zur einmaligen Verwendung (ISO 8536-4:2019)
DIN EN ISO 9626:2016-12	Kanülenrohre aus nichtrostendem Stahl zur Herstellung von Medizinprodukten - Anforderungen und Prüfverfahren (ISO 9626:2016)
DIN ISO 11040-4: 2017-07	Vorgefüllte Spritzen — Teil 4: Spritzenzylinder aus Glas für Injektionspräparate und sterilisierte und vormontierte Spritzen zur Abfüllung
ISO 11040-6: 2019-01	Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling
ISO 11040-8: 2016-11	Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes
DIN EN ISO 11607-1: 2020-05	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019); German version EN ISO 11607-1:2020
DIN EN ISO 11608-1: 2022-09	Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems (ISO 11608-1:2022); German version EN ISO 11608-1:2022
ISO 12189: 2008-05	Implants for surgery — Mechanical testing of implantable spinal

	devices - Fatigue test method for spinal implant assemblies using an anterior support
DIN 13276:2023-08	Kegelverbindungen aus Kunststoff - Beständigkeit gegenüber Spannungsrissbildung
ISO/TS 13498: 2011-08	Dentistry — Torsion test of implant body/connecting part joints of endosseous dental implant systems
ISO 13779-4: 2018-12	Implants for surgery — Hydroxyapatite — Part 4: Determination of coating adhesion strength
ISO 14242-1: 2014-10	Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test
ISO 14242-2: 2016-09	Implants for surgery — Wear of total hip-joint prostheses - Part 2: Methods of measurement
ISO 14243-1: 2009-11	Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test
ISO 14243-2: 2016-09	Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement
ISO 14243-3: 2014-11	Implants for surgery –Wear of total knee joint prostheses – Part 3: Loading and displacement parameters for wear testing machines with displacement control and corresponding environmental conditions for test
ISO 14243-5:2019-05	Implants for surgery — Wear of total knee prostheses — Part 5: Durability performance of the patellofemoral joint
DIN EN ISO 14801: 2017-03	Dentistry - Implants — Dynamic loading test for endosseous dental implants (ISO 14801:2016)
ISO 14879-1: 2020-07	Implants for surgery — Total knee-joint prostheses — Part 1: Determination of endurance properties of knee tibial trays
ISO 18192-1: 2011-03	Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test
DIN EN ISO 20697:2019-04	Sterile Drainagekatheter und Zubehör zur einmaligen Verwendung (ISO 20697:2018, korrigierte Fassung 2018-09)
ISO 22622: 2019-07	Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test
DIN EN ISO 23747: 2015-12	Anaesthetic and respiratory equipment — Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2015); German version EN ISO 23747:2015

DIN EN ISO 80369-1: 2019-08	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2018)
DIN EN ISO 80369-3: 2023-02	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications (ISO 80369-3:2016 + Amd 1:2019)
DIN EN 80369-5: 2017-10	Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications (IEC 80369-5:2016 + Cor. 1:2017)
DIN EN ISO 80369-6: 2018-10	Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications (ISO 80369-6:2016, Corrected version 2016-11-15)
DIN EN ISO 80369-7: 2021-08	Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications
DIN EN ISO 80369-20: 2015-09	Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods
ASTM F88/F88M-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D732-17	Standard Test Method for Shear Strength of Plastics by Punch Tool
ASTM F382-24	Standard Specification and Test Method for Metallic Bone Plates
ASTM F384-24	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
ASTM F543-23	Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F897 – 19	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws
ASTM F1044-05(2017)	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
ASTM F1147-24	Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
ASTM F1160-14(2017)e1	Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
ASTM F1264-24	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F1223-20	Standard Test Method for Determination of Total Knee Replacement Constraint
ASTM F1541-24	Standard Specification and Test Methods for External Skeletal Fixation Devices
ASTM F1714-96(2018)	Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip

	Designs in Simulator Devices
ASTM F1717-21	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1798-24	Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1800-19	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F1814-22	Standard Guide for Evaluating Modular Hip and Knee Joint Components
ASTM F1820-22	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F1875-98(2022)	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2003-02(2022)	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
ASTM F2009-20	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
ASTM F2025-06(2018)	Standard Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment
ASTM F2028-17	Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation
ASTM F2033 - 20	Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials
ASTM F2068-15	Standard Specification for Femoral Prostheses—Metallic Implants
ASTM F2077-22	Test Methods For Intervertebral Body Fusion Devices
ASTM F2083-21	Standard Specification for Knee Replacement Prosthesis
ASTM F2118-14(2020)	Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials
ASTM F2180-24	Standard Specification for Metallic Implantable Strands and Cables
ASTM F2193-20	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
ASTM F2267-24	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2345 – 21	Standard Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

ASTM F2346-18	Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs
ASTM F2423-11(2020)	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses
ASTM F2502-24	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F2582-20	Standard Test Method for Impingement of Acetabular Prostheses
ASTM F2624-12(2020)	Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Spinal Motion Preserving Implants
ASTM F2706-18	Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model
ASTM F2722-21	Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops
ASTM F2723-21	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
ASTM F2724-21	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation
ASTM F2777-23	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
ASTM F3090 – 24	Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement
ASTM F3140-23	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements
ASTM F3210 – 22e1	Standard Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions
ASTM F3446-20	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip implants Using an Anatomical Motion Hip Simulator
S01-2020-11-09	Static expulsion test with intervertebral implants
S02-2020-11-09	Static luxation test with intervertebral implants
S07-2020-11-09	Impaction test with spinal interbody implants
S09-2020-11-09	Standard Specification and Test Method for Metallic Bone Plates Used in Small Bone Fracture Fixation

Abbreviations

ASTM	American Society for Testing and Materials
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DIN	German Institute for Standardization
EN	European Standard
ISO	International Organization for Standardization
Snn-	Internal Test Procedure of SpineServ GmbH & Co. KG (is provided upon request)

For translation:



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