

# Deutsche Akkreditierungsstelle German Accreditation Body

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

Effective from: 17.11.2023

Date of issue: 17.11.2023

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](http://www.dakks.de))*

Abbreviations used: see last page

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

<b>Testing area</b>	<b>Device category</b>	<b>Test method / Test type</b>	<b>Standard method of testing</b>
Chemical Testing	<b>hip joint replacement</b> - modular implant interfaces	determination of requirements  - fretting corrosion testing	ASTM F1875
Physical Testing	<b>dental implants</b>	determination of properties  - fatigue testing of endosseous dental implants - static torsion test	DIN EN ISO 14801  ISO/TS 13498
	<b>partial and total hip joint replacement</b> - 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 - deformation test - determination of the disassembly forces - compression test - fatigue testing - disassembly tests - endurance properties with torsion - endurance properties  - impingement test - wear test - frictional torque	ISO 7206-13 ISO 7206-12 ASTM F2009 ISO 7206-10 ASTM F2068 ASTM F1820 ISO 7206-4 ISO 7206-6  ASTM F2582 ISO 14242-1 ASTM F3446
	<b>infusion and injection accessories</b> - needle-based injection systems - peak flow meter	performance requirement  - dose accuracy  - flow rate	DIN EN ISO 11608-1  DIN EN ISO 23747

Testing area	Device category	Test method / Test type	Standard method of testing
Physical Testing	- connectors	- leakage tests, resistance to separation tests, torsion and tensile tests, strength tests	DIN EN ISO 7886-1 DIN EN ISO 80369-20 applicable: DIN EN ISO 80369-1 ISO 80369-1 DIN EN ISO 80369-3 DIN EN 80369-5 DIN EN ISO 80369-6 DIN EN ISO 80369-7
	- syringes	- pull-off and torsion tests - glide force tests - leakage tests - strength tests - determination of the dead space	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
	<b>knee replacement</b> - tibial tray	determination of properties - fatigue testing	ISO 14879-1 ASTM F1800
- total knee joint replacement	- determination of total knee replacement constraint - mobile bearing rotational stops - dislocation - resistance to dynamic disassociation - fatigue testing under high flexion	ASTM F1223 ASTM F2722 ASTM F2724 ASTM F2723 ASTM F2777	
- total knee joint replacement	- fatigue testing of unicondylar tibial trays - fatigue testing femoral component - disassembly tests	ASTM F3140 S-06 (WK51649) (ISO 7206-4) (ISO 7206-4) ASTM F1814	

Testing area	Device category	Test method / Test type	Standard method of testing
Physical Testing	- total knee joint replacement	- wear testing  - wear assessment  - specifications	ISO 14243-1 ISO 14243-3  ISO 14243-2  ASTM F2083
	<b>ankle replacement</b> - total ankle joint replacement	determination of properties  - wear testing	  ISO 22622
	<b>osteosynthesis implants</b>  - bone plates - small bone plates - bone screws - intramedullary nails - external fixators - metallic angled orthopedic fracture fixation devices - absorbable plates and screws - wires and cables	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  - mechanical testing  - static testing	  ASTM F382 S-09 (WK52025-2017) ASTM F543 ASTM F1264 ASTM F1541 ASTM F384  ASTM F2502  ASTM F2180
	<b>shoulder replacement</b> - glenoid component	determination of properties  - glenoid loosening or disassociation	  ASTM F2028
	<b>sterile barrier and packaging systems</b> - glenoid component	requirements and test methods  - seal strength	DIN EN ISO 11607-1  ASTM F88/F88M
	<b>materials</b> - plastics - bone cement materials - UHMWPE - metallic materials - coatings	determination of properties  - shear strength using punch tool - fatigue testing  - accelerated aging - fatigue testing - adhesion forces	  ASTM D732 ASTM F2118  ASTM F2003 ASTM E466 ISO 13779-4 ASTM F1147

Testing area	Device category	Test method / Test type	Standard method of testing
Physical Testing	<b>spinal Implants</b>	<ul style="list-style-type: none"> <li>- shear and bending strength</li> <li>- shear strength</li> </ul> determination of properties	ASTM F1160 ASTM F1044
	- motion preserving implants	<ul style="list-style-type: none"> <li>- fatigue testing with anterior support</li> <li>- static, dynamic, and wear assessment of extra-discal spinal constructs</li> </ul>	ISO 12189 ASTM F2624
	- internal fixation devices	<ul style="list-style-type: none"> <li>- static and dynamic testing in a vertebrectomy model</li> <li>- static and fatigue properties of subassemblies</li> <li>- static and dynamic testing of single components</li> </ul>	ASTM F1717 ASTM F2706 ASTM F1798 ASTM F2193
	- fusion implants	<ul style="list-style-type: none"> <li>- static and dynamic testing</li> <li>- static expulsion testing</li> <li>- static luxation testing</li> <li>- subsidence testing</li> </ul>	ASTM F2077 S-01 S-02 ASTM F2267
	- surface-coated intervertebral fusion devices	<ul style="list-style-type: none"> <li>- impaction test</li> </ul>	S-07 (ASTM F1044) (ASTM F1147) (ISO 14242-2)
	- spinal artificial discs	<ul style="list-style-type: none"> <li>- static and dynamic testing</li> <li>- static expulsion testing</li> <li>- static luxation testing</li> </ul>	ASTM F2346 S-01 S-02
	- spinal artificial discs	<ul style="list-style-type: none"> <li>- wear testing</li> <li>- determination of the tribological characteristics</li> </ul>	ISO 18192-1 ASTM F2423 ISO 14242-2 ASTM F1714 ASTM F2025

## Set of rules

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: 2018-07	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use (ISO 7886-1:2017)
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: 2015	Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems (ISO/DIS 11608-1:2020); German and English version prEN ISO 11608-1:2020
ISO 12189: 2008-05	Implants for surgery — Mechanical testing of implantable spinal devices - Fatigue test method for spinal implant assemblies using an anterior support
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 14243-3: 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 14243-2: 2016-09	Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement
DIN EN ISO 14801: 2017-03	Dentistry - Implants — Dynamic loading test for endosseous dental implants (ISO 14801:2016)
ISO 14879-1: 2000-06	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
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
ISO 80369-1: 2018-11	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements
DIN EN ISO 80369-1: 2015-09	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements (ISO/DIS 80369-1:2015)
DIN EN ISO 80369-3: 2016-12	Small-bore connectors for liquids and gases in healthcare applications — Part 3: Connectors for enteral applications (ISO 80369-3:2016)
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: 2017-10	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-15	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 F382-17	Standard Specification and Test Method for Metallic Bone Plates
ASTM F384-17	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
ASTM F543-17	Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F1044-05(2017)	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
ASTM F1147-05(2017)	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 F1264-16e1	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F1223-14	Standard Test Method for Determination of Total Knee Replacement Constraint
ASTM F1541-17	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 F1717-18	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1798-13	Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1800-12	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F1814-15	Standard Guide for Evaluating Modular Hip and Knee Joint Components
ASTM F1820-13	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices



ASTM F1875-98(2014)	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2003-02(2015)	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
ASTM F2009-00(2011)	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 F2068-15	Standard Specification for Femoral Prostheses—Metallic Implants
ASTM F2077-18	Test Methods For Intervertebral Body Fusion Devices
ASTM F2083-21	Standard Specification for Knee Replacement Prosthesis
ASTM F2118-14	Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials
ASTM F2180-17	Standard Specification for Metallic Implantable Strands and Cables
ASTM F2193-18a	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
ASTM F2267-04(2018)	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2346-18	Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs
ASTM F2423-11(2016)	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses
ASTM F2502-17	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F2582-14	Standard Test Method for Impingement of Acetabular Prostheses
ASTM F2624-12(2016)	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 F2722-15	Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops
ASTM F2723-13a	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
ASTM F2724-08(2014)	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation

ASTM F2777-16	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
ASTM F3140-17	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements
ASTM F3446-20	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip implants Using an Anatomical Motion Hip Simulator
ASTM E466-15	Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
S01-2020-11-09	Static expulsion test with intervertebral implants
S02-2020-11-09	Static luxation test with intervertebral implants
S06-WK51649-11-09	Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions
S07-2020-11-09	Impaction test with spinal interbody implants
S09-WK52025-11-09	Standard Specification and Test Method for Metallic Bone Plates Used in Small Bone Fracture Fixation

## Abbreviations

ASTM	American Society for Testing and Materials
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:



PD. Dr. Annette Kienle  
(Technical Director)

# Deutsche Akkreditierungsstelle

## Anlage zur Akkreditierungsurkunde D-PL-13415-02-00 nach DIN EN ISO/IEC 17025:2018

**Gültig ab:** 17.11.2023

Ausstellungsdatum: 17.11.2023

Inhaber der Akkreditierungsurkunde:

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

Mit dem Standort:

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

Das Prüflaboratorium erfüllt die Anforderungen gemäß DIN EN ISO/IEC 17025:2018, um die in dieser Anlage aufgeführten Konformitätsbewertungstätigkeiten durchzuführen. Das Prüflaboratorium erfüllt gegebenenfalls zusätzliche gesetzliche und normative Anforderungen, einschließlich solcher in relevanten sektoralen Programmen, sofern diese nachfolgend ausdrücklich bestätigt werden.

Die Anforderungen an das Managementsystem in der DIN EN ISO/IEC 17025 sind in einer für Prüflaboratorien relevanten Sprache verfasst und stehen insgesamt in Übereinstimmung mit den Prinzipien der DIN EN ISO 9001.

### **Chemische und physikalische Prüfungen von Medizinprodukten**

außerhalb einer Anerkennung nach § 18 Medizinprodukte-Durchführungsgesetz.

*Diese Urkundenanlage gilt nur zusammen mit der schriftlich erteilten Urkunde und gibt den Stand zum Zeitpunkt des Ausstellungsdatums wieder. Der jeweils aktuelle Stand der gültigen und überwachten Akkreditierung ist der Datenbank akkreditierter Stellen der Deutschen Akkreditierungsstelle zu entnehmen ([www.dakks.de](http://www.dakks.de))*

Anlage zur Akkreditierungsurkunde D-PL-13415-02-00

Prüfgebiet	Prüfgegenstand Produkt(kategorie)	Prüfungsart Prüfung	Regelwerk Prüfverfahren
Chemische Prüfungen	Hüftgelenkersatz	Prüfung der Anforderungen	
	- Konusverbindung Kopf-Hals	- Korrosion	ASTM F1875
Physikalische Prüfungen	Dentalimplantate	Prüfung der Anforderungen	
		- Dynamische Dauer- Ermüdungsprüfung	DIN EN ISO 14801
		- Torsionstest	ISO/TS 13498
	Hüftgelenkersatz	Prüfung der Anforderungen	
	- Hüftkopf	- Statischer Abdrehversuch	ISO 7206-13
	- Hüftpfanne	- Deformationstest	ISO 7206-12
	- Konusverbindung Kopf-Hals	- statischer Kugelabzug- versuch	ASTM F2009
	- Metallische Hüftgelenkstiele	- Kompressionsversuch	ISO 7206-10
	- Mechanische Festigkeit	ASTM F2068	
	- Modulare Hüftpfannen	- Bestimmung der Haltekräfte	ASTM F1820
	- Prothesenschäfte	- Dauerschwingprüfung mit Torsionsbeanspruchung	ISO 7206-4
	- Prothesenschäfte (Kopf- und Halsregion)	- Dauerschwingprüfung	ISO 7206-6
	- Totaler Hüftgelenk- ersatz	- Impingementversuch	ASTM F2582
		- Verschleißtest	ISO 14242-1
		- Bestimmung der Reibmomente	ASTM F3446
	Infusions- und Injektionszubehör	Prüfung der Anforderungen	
	- Kanülenbasierte Injektionssysteme	- Prüfung der Dosiergenauigkeit	DIN EN ISO 11608-1
	- Spirometer	- Messung der Flussrate	DIN EN ISO 23747

Anlage zur Akkreditierungsurkunde D-PL-13415-02-00

Prüfgebiet	Prüfgegenstand Produkt(kategorie)	Prüfungsart Prüfung	Regelwerk Prüfverfahren
Physikalische Prüfungen	Infusions- und Injektionszubehör - Konnektoren	Prüfung der Anforderungen - Abzugs- und Torsionsversuche, Dichtigkeitsprüfungen, Festigkeitsprüfungen	DIN EN ISO 7886-1 DIN EN ISO 80369-20  Mitgeltend: DIN EN ISO 80369-1 ISO 80369-1 DIN EN ISO 80369-3 DIN EN 80369-5 DIN EN ISO 80369-6 DIN EN ISO 80369-7
	- Spritzen  - Vorgefüllte Spritzen	- Abzugs- und Torsionsversuche, Ausdrückversuche, Dichtigkeitsprüfungen, Festigkeitsprüfungen, Messung des Totraumvolumens  - Abzugs- und Torsionsversuche, Ausdrückversuche, Dichtigkeitsprüfungen, Festigkeitsprüfungen, Messung des Totraumvolumens	DIN EN ISO 7886-1  DIN ISO 11040-4 ISO 11040-6 ISO 11040-8
	Kniegelenkimplantate - Tibiaplateaus - Totaler Kniegelenkersatz	Prüfung der Anforderungen - Bestimmung des Ermüdungsverhaltens - Bestimmung der Freiheitsgrade - Bestimmung von Rotationsanschlägen - Dislokation - Dynamische Dissoziation - Ermüdung und Deformation unter Belastung bei starker Flexion	ISO 14879-1 ASTM F1800 ASTM F1223  ASTM F2722  ASTM F2724 ASTM F2723 ASTM F2777

Anlage zur Akkreditierungsurkunde D-PL-13415-02-00

Prüfgebiet	Prüfgegenstand Produkt(kategorie)	Prüfungsart Prüfung	Regelwerk Prüfverfahren
Physikalische Prüfungen	Kniegelenkimplantate - Totaler Kniegelenkersatz	Prüfung der Anforderungen - Ermüdungstest unikondyläres Tibiaplateau - Ermüdungstest Femurkomponente - Prüfung der Modularverbindungen - Verschleißtest - Verschleißtest Messmethoden - Spezifikationen	ASTM F3140 S-06 (WK51649) (ISO 7206-4) (ISO 7206-6) ASTM F1814 ISO 14243-1 ISO 14243-3 ISO 14243-2 ASTM F2083
	Sprunggelenkimplantate - Totaler Sprunggelenkersatz	Prüfung der Anforderungen - Verschleißtest	ISO 22622
	Osteosyntheseimplantate - Knochenplatten - Knochenschrauben - Nägel - Fixateur extern - gewinkelte Osteosynthesysteme - absorbierbare Platten und Schrauben - Drähte	Prüfung der Anforderungen - Statisches und dynamisches Biegeverhalten - Torsions-Biegeversuch - Prüfung des Biege- und Torsionsverhalten - Biege-Torsionsversuch - Biegeversuch - statische Prüfungen - statische Prüfungen	ASTM F382 S-09 (WK52025-2017) ASTM F543 ASTM F1264 ASTM F1541 ASTM F384 ASTM F2502 ASTM F2180
	Schultergelenkersatz - Glenoidkomponenten	Prüfung der Anforderungen - Lockerungs- und Dissoziationstests	ASTM F2028

Anlage zur Akkreditierungsurkunde D-PL-13415-02-00

Prüfgebiet	Prüfgegenstand Produkt(kategorie)	Prüfungsart Prüfung	Regelwerk Prüfverfahren
Physikalische Prüfungen	Sterilbarriere- und Verpackungssysteme, Materialien	Prüfungen im Rahmen des Nachweises der Überein- stimmung  - Siegelfestigkeit	DIN EN ISO 11607-1  ASTM F88/F88M
	Werkstoffe für die Endoprothetik  - Kunststoff  - Knochenzement  - UHMWPE  - Metallische Werkstoffe  - Beschichtungen	Bestimmung der Materialeigenschaften  - Scherfestigkeit durch Stanzgerät  - Dynamische Zug- Druckversuche  - Beschleunigte Alterung  - Ermüdungsversuche  - Bestimmung der Adhäsionskräfte  - Scher- und Biegefestigkeit  - Scherfestigkeit	ASTM D732  ASTM F2118  ASTM F2003 ASTM E466  ISO 13779-4 ASTM F1147 ASTM F1160 ASTM F1044
	Wirbelsäulenimplantate  - Bewegungserhaltende Systeme          - Fixateure	Prüfung der Anforderungen  - Ermüdungsprüfung mit anteriorer Unterstützung  - Prüfung des statischen, dynamischen und Verschleißverhaltens von extra diskalen bewegungs- erhaltenden Wirbelsäulen- implantaten  - Statische und dynamische Festigkeitsversuche  - Statische und dynamische Prüfung von Verbindungs- elementen von Arthrodesimplantaten  - Spezifikationen sowie statische und dynamische Prüfungen	ISO 12189  ASTM F2624  ASTM F1717 ASTM F2706 ASTM F1798  ASTM F2193

Anlage zur Akkreditierungsurkunde D-PL-13415-02-00

Prüfgebiet	Prüfgegenstand Produkt(kategorie)	Prüfungsart Prüfung	Regelwerk Prüfverfahren
Physikalische Prüfungen	- Fusionsimplantate	- Statische und dynamische Prüfung	ASTM F2077 S-01 S-02
		- Prüfung des Einsinkverhaltens unter statischer Axiallast	ASTM F2267
	- beschichtete Fusionsimplantate	- Einhämmerversuch	S-07 ASTM F1044) (ASTM F1147) (ISO 14242-2)
	- Bandscheibenimplantate	- Statische und dynamische Prüfung	ASTM F2346 S-01 S-02
		- Verschleißprüfung	ISO 18192-1 ASTM F2423
		- Bestimmung der tribologischen Eigenschaften (Verschleißprüfungen)	ISO 14242-2 ASTM F1714 ASTM F2025

**Quellenverzeichnis Regelwerke/Prüfverfahren:**

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



**Anlage zur Akkreditierungsurkunde D-PL-13415-02-00**

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: 2018-07	Sterile Einmalspritzen für medizinische Zwecke - Teil 1: Spritzen zum manuellen Gebrauch (ISO 7886-1:2017)
DIN ISO 11040-4: 2017-07	Vorgefüllte Spritzen - Teil 4: Spritzenzylinder aus Glas für Injektionspräparate und sterilisierte und vormontierte Spritzen zur Abfüllung (ISO 11040-4:2015)
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	Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme (ISO 11607-1:2019)
DIN EN ISO 11608-1: 2015	Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 1: Kanülenbasierte Injektionssysteme(ISO 11608-1:2014)
ISO 12189: 2008-05	Implants for surgery - Mechanical testing of implantable spinal devices - Fatigue test method for spinal implant assemblies using an anterior support
ISO/TS 13498: 2011-08	Dentistry -- Torsion test of implant body/connecting part joints of endosseous dental implant systems
ISO 13779-4: 2018	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

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	with displacement control and corresponding environmental conditions for test
DIN EN ISO 14801: 2017-03	Zahnheilkunde - Implantate - Dynamische Belastungsprüfung für enossale Dentalimplantate (ISO 14801:2016);
ISO 14879-1: 2000-06	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
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	Anästhesie- und Beatmungsgeräte - Spirometer für den expiratorischen Spitzenfluss zur Bewertung der Lungenfunktion bei spontan atmenden Menschen(ISO 23747:2015)
ISO 80369-1: 2018-11	Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements
DIN EN ISO 80369-1: 2015-09	Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 1: Allgemeine Anforderungen (ISO 80369-1:2010);
DIN EN ISO 80369-3:2016-12	Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 3: Verbindungsstücke für enterale Anwendungen (ISO 80369-3:2016)
DIN EN 80369-5:2017-10	Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 5: Verbindungsstücke für Anwendungen mit aufblasbaren Manschetten systemen für Gliedmaßen
DIN EN ISO 80369-6: 2018-10	Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 6: Verbindungsstücke für neuroaxiale Anwendungen
DIN EN ISO 80369-7: 2017-10	Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 7: Verbindungsstücke mit einem 6% (Luer) Kegel für intravaskuläre oder hypodermische Anwendungen (ISO 80369-7:2016, korrigierte Fassung 2016-12-01);
DIN EN ISO 80369-20: 2015-09	Verbindungsstücke mit kleinem Durchmesser für Flüssigkeiten und Gase in medizinischen Anwendungen - Teil 20: Allgemeine Prüfverfahren (ISO 80369-20:2015);
ASTM F88/F88M – 15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM D732 – 17	Standard Test Method for Shear Strength of Plastics by Punch Tool

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ASTM F382 – 17	Standard Specification and Test Method for Metallic Bone Plates
ASTM F384-17	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices
ASTM F543 – 17	Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F1044 – 05(2017)	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
ASTM F1147-05(2017)	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 – 16e1	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F1223-14	Standard Test Method for Determination of Total Knee Replacement Constraint
ASTM F1541 – 17	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 – 18	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1798 – 13	Standard Test Methods for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1800 – 12	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F1814-15	Standard Guide for Evaluating Modular Hip and Knee Joint Components
ASTM F1820 – 13	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F1875 – 98(2014)	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface
ASTM F2003-02(2015)	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
ASTM F2009 – 00(2011)	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses

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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 F2068 – 15	Standard Specification for Femoral Prostheses—Metallic Implants
ASTM F2077 – 18	Test Methods For Intervertebral Body Fusion Devices
ASTM F2083 - 21	Standard Specification for Knee Replacement Prosthesis
ASTM F2118 – 14	Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials
ASTM F2180-17	Standard Specification for Metallic Implantable Strands and Cables
ASTM F2193 – 18a	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
ASTM F2267 – 04(2018)	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2346 – 18	Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs
ASTM F2423 – 11(2016)	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses
ASTM F2502-17	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F2582-14	Standard Test Method for Impingement of Acetabular Prostheses
ASTM F2624 – 12(2016)	Standard Test Method for Static, Dynamic, and Wear Assessment of Extra-Discal Single Level Spinal Constructs
ASTM F2706 – 18	Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model
ASTM F2722-15	Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops
ASTM F2723-13a	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation
ASTM F2724-08(2014)	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation
ASTM F2777-16	Standard Test Method for Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion
ASTM F3140-17	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements

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ASTM F3446-20	Standard Test Method for Determination of Frictional Torque and Friction Factor for Hip Implants Using an Anatomical Motion Hip Simulator
ASTM E466 – 15	Standard Practice for Conducting Force Controlled Constant Amplitude Axial Fatigue Tests of Metallic Materials
S01-2020-11-09	Static expulsion test with intervertebral implants
S02-2020-11-09	Static luxation test with intervertebral implants
S06-WK51649-11-09	Standard Test Method for Fatigue Testing of Total Knee Femoral Components under Closing Conditions
S07-2020-11-09	Impaction test with spinal interbody implants
S09-WK52025-11-09	Standard Specification and Test Method for Metallic Bone Plates Used in Small Bone Fracture Fixation

**Abkürzungen**

ASTM	American Society for Testing and Materials
DIN	Deutsches Institut für Normung
EN	Europäische Norm
ISO	International Organization for Standardization
Snn-	Regelwerke der SpineServ GmbH & Co. KG (stehen auf Anfrage zur Verfügung)