

Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-18753-02-00 according to DIN EN ISO/IEC 17025:2018

Valid from: 23.05.2023

Date of issue: 23.05.2023

This annex is a part of the accreditation certificate D-PL-18753-02-00.

Holder of partial accreditation certificate:

Questmed GmbH
Albert-Einstein-Ring 9, 14532 Kleinmachnow

with its testing laboratory

Questmed GmbH
Albert-Einstein-Ring 9, 14532 Kleinmachnow

Questmed GmbH
Ilmstraße 18, 07743 Jena

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

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

Physical and physical-chemical testing of non-active implants

This certificate annex is only valid together with the written accreditation certificate and reflects the status as indicated by the date of issue. The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de>.

Location Albert-Einstein-Ring 9, 14532 Kleinmachnow

Testing Area	Test item Device (category)	Type of testing Test	Regulation Testing method	
Physical testing	Dental implants	Fatigue test	DIN EN ISO 14801	
	Cardiovascular implants - Occluder	Durability under axial and hydrodynamic load	ISO 22679 ASTM F3211	
	Knee - joint implants	Requirements testing		
		Determination of geometric data and classification		ISO 7207-1
		Determination of tribological properties in the knee simulator		ISO 14243-1 ISO 14243-2 ISO 14243-3 ASTM F3141
	Fatigue test Endurance Durability		ISO 14879-1 DIN EN ISO 21536 ASTM F1800 ASTM F2083	
	PE accelerated aging		ISO 5834-3 ASTM F2003	
	Testing of standard specification for knee replacement prosthesis		ASTM F2083, Chapter 6.3.1 and 6.4	
	Osteosynthesis implants	Requirements testing Static and dynamic strength tests	AW-17 Co-applicable: ASTM F382 ASTM F1717	

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Testing Area	Test item Device (category)	Type of testing Test	Regulation Testing method
Physical testing	Osteosynthesis implants		
	<ul style="list-style-type: none"> - Bone plates - Bone screws - Intramedullary Fixation Devices 	<ul style="list-style-type: none"> Bending strenght - Torsion test - Bending test - Insertion/removal torque - Pullout strength - Torsion test - Bending test 	<ul style="list-style-type: none"> ASTM F382 ASTM F543 ASTM F1264
	Hip-joint implants	<ul style="list-style-type: none"> Requirements testing Determination of geometric data and classification General requirements Determination of endurance properties and performance of hip endoprosthesis stems Endurance properties of prosthesis stems with torsional loading Endurance properties <ul style="list-style-type: none"> - Head and neck region - Bearing balls 	<ul style="list-style-type: none"> ISO 7206-1 ASTM F2068 ISO 7206-4 AW-03 Co-applicable: ASTM F2068 ISO 7206-6

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Testing Area	Test item Device (category)	Type of testing Test	Regulation Testing method
Physical testing	Shoulder implants	Requirements testing	
	- Shoulder endoprotheses	Wear of shoulder endoprotheses	AW-13 Co-applicable: ASTM F1378 ASTM F1829 ASTM F2028 DIN EN ISO 10523
		Static and dynamic strength test of shoulder endoprotheses	AW-18 Applicable: ASTM F1829 ASTM F2028
	Elbow implants	Requirements testing	
		Wear testing Endurance properties	ASTM F2887
	Foot implants	Requirements testing	
		Wear of ankle endoprotheses	ISO 22622 ASTM F2665
	Spinal implants	Requirements testing	
	- Fixators	- Static and dynamic strength test - Static and fatigue test of interconnection mechanisms used in Spinal Arthrodesis Implants (without torsion test) - Specifications and static and dynamic test	ASTM F1717 ASTM F1798 ASTM F2193

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Testing Area	Test item Device (category)	Type of testing Test	Regulation Testing method
Physical testing	Spinal implants	Static and dynamic tests	ASTM F2077
	- Intervertebral body fusion devices	Subsidence under static axial compression	ASTM F2267
Physical-chemical testing	Metallic implants	Ion Release Evaluation of Medial Implants	ASTM F3306
	Dental implants	Corrosion test - Sulfide tarnish test (cyclic immersion) - Sulfide tarnish test (static immersion) - Preparation and sampling for static immersion test	DIN EN ISO 10271

Location Ilmstraße 18, 07743 Jena

Testing Area	Test item Device (category)	Type of testing Test	Regulation Testing method
Physical testing	Dental implants	Fatigue test	DIN EN ISO 14801
		Detraction test for frictional retention elements	AW-25 (DIN EN ISO 13017)
		Magnetic attachments	DIN EN ISO 13017
	Cardiovascular implants		
	- Occluder	Durability under axial and hydrodynamic load	ISO 22679 ASTM F3211
- Stents	Fatigue test Durability	DIN EN ISO 25539-1 DIN EN ISO 25539-2 ASTM F3211	
- Vena cava filters	Fatigue test Durability	DIN EN ISO 25539-3 ASTM F3211	
Knee-joint prostheses		Fatigue test Endurance Durability	ISO 14879-1 DIN EN ISO 21536 ASTM F1800 ASTM F2083
		Testing of standard specification for knee replacement prosthesis	ASTM F2083, Chapter 6.3.1 and 6.4
Osteosynthesis implants		Requirements testing	
		Static and dynamic strength tests	AW-17 Co-applicable: ASTM F382 ASTM F1717
	- Bone plates	Bending strenght	ASTM F382

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Testing Area	Test item Device (category)	Type of testing Test	Regulation Testing method
Physical testing	Hip-joint prostheses	Requirements testing	
		Determination of geometric data and classification	ISO 7206-1
		Determination of endurance properties and performance of stemmed femoral components	ISO 7206-4
Physical testing	Spinal implants - Fixators	Requirements testing	
		Static and dynamic strength test	ASTM F1717
		Endurance properties - Head and neck region - Bearing balls	ISO 7206-6
Physical testing	Medical gloves	Requirements and testing for freedom from holes	DIN EN 455-1
Physical-chemical testing	Metallic implants	Ion Release Evaluation of Medial Implants	ASTM F3306
	Dental implants	Corrosion test - Sulfide tarnish test (cyclic immersion) - Sulfide tarnish test (static immersion) - Preparation and sampling for static immersion test	DIN EN ISO 10271

Regulations:

DIN EN 455-1 : 2020-07	Medical gloves for single use - Part 1: Requirements and testing for freedom from holes; German version EN 455-1:2020
ISO 5834-3 : 2019-02	Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 3: Accelerated ageing methods
ISO 7206-1 : 2008-04	Implants for surgery - Partial and total hip joint prostheses - Part 1: Classification and designation of dimensions
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. + Amendment 1, 2016-03
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 7207-1 : 2007-02	Implants for surgery - Components for partial and total knee joint prostheses - Part 1: Classification, definitions and designation of dimensions
DIN EN ISO 10271 : 2020-12	Dentistry - Corrosion test methods for metallic materials (ISO 10271:2020); German version EN ISO 10271:2020
DIN EN ISO 10523 : 2012-04	Water quality - Determination of pH (ISO 10523:2008); German version EN ISO 10523:2012
DIN EN ISO 13017 : 2020-10	Dentistry - Magnetic attachments (ISO 13017:2020); German version EN ISO 13017:2020
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. + Amendment 1, 2020-01
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. + Amendment 1, 2020-01
DIN EN ISO 14801 : 2017-03	Dentistry - Implants - Dynamic loading test for endosseous dental implants (ISO 14801:2016); German version EN 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

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DIN EN ISO 21536 : 2014-07	Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants (ISO 21536:2007 + Amd.1:2014); German version EN ISO 21536:2009 + A1:2014
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
ISO 22679 :2021-11	Cardiovascular implants - Transcatheter cardiac occluders
DIN EN ISO 25539-1 : 2018-05	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017); German version EN ISO 25539-1:2017
DIN EN ISO 25539-2 : 2021-01	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2020); German version EN ISO 25539-2: 2020
DIN EN ISO 25539-3 : 2012-03	Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters (ISO 25539-3:2011); German version EN ISO 25539-2: 2011
ASTM F382 - 17	Standard Specification and Test Method for Metallic Bone Plates
ASTM F543 - 17	Standard Specification and Test Method for Metallic Bone Screws
ASTM F1264 - 16e1	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F1378 - 18e1	Standard Specification for Shoulder Prostheses
ASTM F1717 - 21	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1798 - 21	Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F1800 - 19e1	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F1829 - 17	Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear
ASTM F1839 - 08 (2021)	Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopedic Devices and Instruments
ASTM F2003 - 02 (2015)	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
ASTM F2028 - 17	Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation

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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 F2193 - 20	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 an Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F2665 - 21	Standard Specification for Total Ankle Replacement Prosthesis
ASTM F2887 - 17	Standard Specification for Total Elbow Prostheses
ASTM F3141 - 17a	Standard Guide for Total Knee Replacement Loading Profiles
ASTM F3211 - 17	Standard Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices
ASTM F3306 - 19	Standard Test Method for Ion Release Evaluation of Medial Implants
AW-03 : 2021-01	Endurance properties of stemmed femoral components with torsional loading
AW-10 : 2021-10	Pull out resistance in the expulsion test
AW-13 : 2022-04	Wear of shoulder endoprotheses
AW-17 : 2018-10	Static and dynamic strength testing of osteosynthesis systems
AW-18 : 2016-06	Static and dynamic strength testing of shoulder endoprotheses
AW-25 : 2021-10	Detraction test for frictional retention elements

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Abbreviations used:

ASTM	American Society for Testing and Materials
AW	In house method of Questmed GmbH
DIN	Deutsches Institut für Normung (German Institute for Standardization)
EN	Europäische Norm (European standard)
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission