

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18753-02-00 according to DIN EN ISO/IEC 17025:2018¹

Valid from: 04.03.2020

Date of issue: 04.03.2020

Holder of certificate:

Questmed GmbH

at the sites

Albert-Einstein-Ring 9, 14532 Kleinmachnow

Ilmstraße 18, 07743 Jena

Field: Medical devices and the Directive 93/42/EEC²

Testing fields/test items: Physical and physical-chemical testing of non-active implants

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

*The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<https://www.dakks.de/en/content/accredited-bodies-dakks>*

Site Albert-Einstein-Ring 9, 14532 Kleinmachnow

Field of testing	Test object Product (category)	Type of testing Test performed	Standard Test procedure	
Physical testing	Dental implants	Fatigue test Detraction test for frictional retention elements	DIN EN ISO 14801 AW-25	
	Cardiovascular implants Occluder	Durability under axial and hydrodynamic load	AW-16 Co-applicable: DIN EN ISO 25539-1 DIN EN ISO 25539-2	
	Knee-joint prostheses	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 testing		ISO 14879-1 DIN EN ISO 21536 ASTM F1800		
PE accelerated ageing		ISO 5834-3 ASTM F2003		
Physical testing	Osteosynthesis implants	Requirements testing Static and dynamic strength tests	AW-17 Co-applicable: ASTM F382 ASTM F1717	
	Bone plates	Bending strenght	ASTM F382	
Physical testing	Osteosynthesis implants Bone screws	Requirements testing Torsion bending test Insertion/removal torque Pullout strength	ASTM F543	

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Field of testing	Test object Product (category)	Type of testing Test performed	Standard Test procedure
Physical testing	Hip-joint prostheses	Requirements testing Determination of geometric data and classification General requirements Determination of endurance properties and performance of stemmed femoral components Endurance properties of stemmed femoral components with torsional loading Endurance properties Head and neck region Bearing balls	ISO 7206-1 ASTM F2068 ISO 7206-4 AW-03 Co-applicable: ASTM F2068 ISO 7206-6
	Shoulder implants Shoulder endoprotheses	Requirements testing Wear of shoulder endoprotheses	AW-13 Co-applicable: ASTM F1378 ASTM F1829 ASTM F2028 DIN ISO 10523
Physical testing	Shoulder implants	Requirements testing Static and dynamic strength test of shoulder endoprotheses	AW-18 Co-applicable: ASTM F1829 ASTM F2028
	Foot implants	Requirements testing Wear of ankle endoprotheses	AW-15 Co-applicable: ISO 14243-1 ISO 14243-2 ASTM F2665

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Field of testing	Test object Product (category)	Type of testing Test performed	Standard Test procedure
Physical testing	Spinal implants Fixators	Requirements testing Static and dynamic strength test Specifications and static and dynamic test	ASTM F1717 ASTM F2193
	Intervertebral body fusion devices	Static and dynamic tests Subsidence under static axial compression Pull out resistance in the expulsion test	ASTM F2077 ASTM F2267 AW-10 Co-applicable: ASTM F2077 ASTM F2267 ASTM F1839
Physical-chemical testing	Metallic implants	Standard Test Method for Ion Release Evaluation of Medical 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

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Physical testing	Dental implants	Fatigue test Detraction test for frictional retention elements	DIN EN ISO 14801 AW-25
	Cardiovascular implants Occluder	Durability under axial and hydrodynamic load	AW-16 Co-applicable: DIN EN ISO 25539-1 DIN EN ISO 25539-2

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Field of testing	Test object Product (category)	Type of testing Test performed	Standard Test procedure
Physical-chemical testing	Metallic implants	Standard Test Method for Ion Release Evaluation of Medical 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

Reference standards

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
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 : 2011-10	Dentistry - Corrosion test methods for metallic materials (ISO 10271:2011); Deutsche Fassung EN ISO 10271:2011
DIN EN ISO 10523 : 2012-04	Water quality - Determination of pH
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

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DIN EN ISO 14801 : 2017-03	Dentistry - Implants - Dynamic loading test for endosseous dental implants (ISO 14801:2016); Deutsche Fassung EN 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
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); Deutsche Fassung EN ISO 21536:2009 + A1:2014
DIN EN ISO 25539-1 : 2018-05	Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017); Deutsche Fassung EN ISO 25539-1:2017
DIN EN ISO 25539-2 : 2013-05	Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2012); Deutsche Fassung EN ISO 25539-2:2012
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 F1378 - 18	Standard Specification for Shoulder Prostheses
ASTM F1717 - 18	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
ASTM F1800 - 12	Standard Test Method 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 (2016)	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
ASTM F2068 - 15	Standard Specification for Femoral Prostheses - Metallic Implants
ASTM F2077 - 18	Test Methods For Intervertebral Body Fusion Devices
ASTM F2193 - 14	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

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ASTM F2665 - 09 (2014)	Standard Specification for Total Ankle Replacement Prosthesis
ASTM F3306 - 19	Standard Test Method for Ion Release Evaluation of Medial Implants
ASTM F3141 - 17a	Standard Guide for Total Knee Replacement Loading Profiles
AW-03 : 2016-06	Endurance properties of stemmed femoral components with torsional loading
AW-10 : 2018-10	Pull out resistance in the expulsion test
AW-13 : 2018-10	Wear of shoulder endoprotheses
AW-15 : 2018-10	Wear of ankle joint endoprotheses
AW-16 : 2018-10	Durability testing of occluder implants under axial and hydrodynamic loading
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 : 2018-10	Detraction test for frictional retention elements

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

¹ DIN EN ISO/IEC 17025 : 2018-03 General requirements for the competence of testing and calibration laboratories

² Council Directive 93/42/EEG of 14 June 1993 concerning medical devices

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