

Enclosure concerning to the recognition notice from 2020-03-04 about the

## Recognition

of Questmed GmbH  
Albert-Einstein-Ring 9  
14532 Kleinmachnow  
Germany

sites Albert-Einstein-Ring 9  
14532 Kleinmachnow

Ilmstr. 18  
07743 Jena

Managing Director Steffen Vater

as testing laboratory for medical devices complying to the Council Directive 93/42/EEC<sup>1</sup>  
and EN ISO/IEC 17025<sup>2</sup>

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Registration number **ZLG-AP-225.10.75**

## Limitation

The Recognition is valid up to 2023-05-28.

## Licence Scope

**Site Albert-Einstein-Ring 9 , 14532 Kleinmachnow , Germany**

Testing categories	Device category	Characteristics/ Test options	Standard method of testing
Physical testing	Dental implants	Fatigue test Detraction test for frictional retention elements	DIN EN ISO 14801 AW-25



Testing categories	Device category	Characteristics/ Test options	Standard method of testing
Physical testing	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  Determination of tribological properties in the knee simulator  Fatigue testing  PE accelerated ageing	ISO 7207-1  ISO 14243-1 ISO 14243-2 ISO 14243-3 ASTM F3141  ISO 14879-1 DIN EN ISO 21536 ASTM F1800  ISO 5834-3 ASTM F2003
	Osteosynthesis implants  - Bone plates - Bone screws  Hip-joint prostheses	Requirements testing  Static and dynamic strength tests  Bending strenght - Torsion bending test - Insertion/removal torque - Pullout strength  Requirements testing  Determination of geometric data and classification  General requirements  Determination of endurance properties and performance of stemmed femoral components	AW-17 Co-applicable: ASTM F382 ASTM F1717  ASTM F382 ASTM F543  ISO 7206-1  ASTM F2068  ISO 7206-4



Testing categories	Device category	Characteristics/ Test options	Standard method of testing
Physical testing	Hip-joint prostheses	Endurance properties of stemmed femoral components with torsional loading  Endurance properties - Head and neck region - Bearing balls	AW-03 Co-applicable: ASTM F2068  ISO 7206-6
	Shoulder implants - Shoulder endoprostheses	Requirements testing  Wear of shoulder endoprostheses    Static and dynamic strength test of shoulder endoprostheses	AW-13 Co-applicable: ASTM F1378 ASTM F1829 ASTM F2028 DIN ISO 10523  AW-18 Co-applicable: ASTM F1829 ASTM F2028
	Foot implants	Requirements testing  Wear of ankle endoprostheses	AW-15 Co-applicable: ISO 14243-1 ISO 14243-2 ASTM F2665
	Spinal implants - Fixators   - Intervertebral body fusion devices	Requirements testing  Static and dynamic strength test  Specifications and static and dynamic test  Static and dynamic tests  Subsidence under static axial compression  Pull out resistance in the expulsion test	ASTM F1717  ASTM F2193  ASTM F2077  ASTM F2267  AW-10 Co-applicable: ASTM F2077 ASTM F2267 ASTM F1839



Testing categories	Device category	Characteristics/ Test options	Standard method of testing
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

**Site Ilmstraße 18, 07743 Jena, Germany**

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Physical testing	Dental implants	Fatigue test Detraction test for frictional retention elements	DIN EN ISO 14801 AW-25
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## Set of Rules (not translated)<sup>3</sup>

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	Zahnheilkunde - Korrosionsprüfverfahren für metallische Werkstoffe (ISO 10271:2011); Deutsche Fassung EN ISO 10271:2011
DIN EN ISO 10523 : 2012-04	Wasserbeschaffenheit –Bestimmung des pH-Werts
ISO 14243-1 : 2009-11	Chirurgische Implantate - Verschleissverhalten totaler Knieendoprothesen - Teil 1: Belastungs- und Bewegungsparameter für lastgesteuerte Verschleissprüfmaschinen und zugeordnete Prüfbedingungen
ISO 14243-2 : 2016-09	Chirurgische Implantate - Verschleiß totaler Kniegelenkendoprothesen - Teil 2: Messmethoden
ISO 14243-3 : 2014-11	Chirurgische Implantate - Verschleissverhalten totaler Knieendoprothesen - Teil 3: Belastungs- und Verschiebungsparameter für Verschleissprüfmaschinen mit Wegregelung und entsprechenden Umgebungsbedingungen für die Prüfung
DIN EN ISO 14801 : 2017-03	Zahnheilkunde - Implantate - Dynamische Belastungsprüfung für enossale Dentalimplantate (ISO 14801:2016); Deutsche Fassung EN ISO 14801:2016
ISO 14879-1 : 2000-06	Chirurgische Implantate - Totale Knieendoprothesen - Teil 1: Bestimmung des Belastungsverhaltens von Tibiaunterlagen zum Kniegelenkersatz
DIN EN ISO 21536 : 2014-07	Nichtaktive chirurgische Implantate - Implantate zum Gelenkersatz - Besondere Anforderungen an Implantate für den Kniegelenkersatz (ISO 21536:2007 + Amd.1:2014); Deutsche Fassung EN ISO 21536:2009 + A1:2014
DIN EN ISO 25539-1 : 2018-05	Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2017); Deutsche Fassung EN ISO 25539-1:2017

DIN EN ISO 25539-2 : 2013-05	Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 2: Gefäßstents (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
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	Belastbarkeit von Prothesenschäften mit Torsionsbeanspruchung
AW-10 : 2018-10	Widerstand eines Wirbelkörperimplantates gegen Verschiebung, „Expulsion Test“
AW-13 : 2018-10	Verschleißprüfung von Schulterendoprothesen
AW-15 : 2018-10	Verschleißprüfung von Sprunggelenkendoprothesen

AW-16 : 2018-10	Prüfung der Dauerhaltbarkeit von Okkluder Implantaten bei axialer und hydrodynamischer Belastung
AW-17 : 2018-10	Statische und dynamische Festigkeitsprüfung an Osteosynthese-Systemen
AW-18 : 2016-06	Statische und dynamische Festigkeitsprüfung von Schulter-endoprothesen
AW-25 : 2018-10	Kappenabzugsprüfung zur Bestimmung der Haltekraft von dentalen Steckimplantaten

## Abbreviations (not translated)

ASTM	American Society for Testing and Materials
AW	Hausinterne Arbeitsanweisung der Questmed GmbH
DIN	Deutsches Institut für Normung
EN	Europäische Norm
ISO	International Organization for Standardization

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<sup>1</sup> Council Directive 93/42/EEG of 14 June 1993 concerning medical devices

<sup>2</sup> EN ISO/IEC 17025 : 2018-03 General requirements for the competence of testing and calibration laboratories

<sup>3</sup> For transition periods see list of harmonised standards under Union harmonisation legislation