

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13119-01-00 according to DIN EN ISO/IEC 17025:2018¹

Valid from: 20.05.2020

Date of issue: 05.02.2021

Holder of certificate:

**IMA Materialforschung und Anwendungstechnik GmbH
Wilhelmine-Reichard-Ring 4, 01109 Dresden**

at the locations:

**Labor für Medizinprodukteprüfung
Am Lagerplatz 4, 01099 Dresden
Wilhelmine-Reichard-Ring 4, 01109 Dresden**

Field: Medical devices with the provision of fulfilling the requirements of the Medical Device Directive (Council Directive) 93/42/EEC² regarding independence

Testing fields/test items: Physical testing of medical devices and implants as well as visual testing of 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>*

Scope at the location Am Lagerplatz 4:

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical tests	Surgical implants	Testing against the requirements Dimensions and proportion measurements	DIN EN ISO 14630
	Knee joints implants - Articulating surfaces - Femoral components - Femur components - Knee joints endoprothetics - Tibial plateaus - Metallic porous coatings	Testing against the requirements Determination of contact surface and the pressure distribution Abrasion Finite-Element-Analyse Dynamic strength tests Determination of degrees of freedom Determination of tribological properties in knee simulator Endurance Fatigue tests Fatigue tests unicondyar implants Shear testing Tension testing Shear and bending testing	IMA-PV C/30 ISO 7207-2 ASTM F 3161 IMA-PV C/31 ASTM F1223 ISO 14243-1 ISO 14243-2 ISO 14243-3 ASTM F 1800 ISO 14879-1 IMA PV C/38 ASTM F 3140 ASTM F 1044 ASTM F1147 ASTM F 1160
Physical tests	Partial and total hip joint replacements/prostheses - Articulating surfaces	Testing against the requirements Strength of modular connections roundness and abrasive testing	ASTM F 2009 ASTM F 2345 ISO 7206-2

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	- Hip joint endoprotheses	Determination of tribological properties in hip simulator	ISO 14242-1 ISO 14242-2
Physical tests	- Hip joint heads	Resistance against torsion stress	ISO 7206-13
	- Hip joint sockets	Impingement-Simulation Static Deformation measurement	ASTM F 2582 ISO 7206-12
	- Ceramic balls and ceramic pairings	Dynamic strength test	IMA-PV C/25
	- Metallic hip joint shafts	Testing against the requirements - Mechanical strength	ASTM F 2068
	- Modular hip joint sockets	Determination of fixation force between socket insert and shell	ASTM F 1820
	- Modular hip joint shafts	Rubbing corrosions-test - Method I - Long term testing	ASTM F 1875
Physical tests	Osteosynthetic implants	Testing against requirements	
	- Slide pairings Discs - balls	Wear test with oscillating loads in prototype equipment	IMA-PV C/29
	- Intramedullar nails and medullar pins	Dimensions Static and dynamic strength	ISO 5837-1 ASTM F 1264
	- Kirschner skeleton wires	Dimensions	ISO 5838-3
	- Bone discs	Bending strength Rigidity	ISO 9585 ASTM F 382
		Dimensions	ISO 5836
	- Bone screws	Mechanical requirements and tests	ISO 6475 ASTM F 543

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	- Absorbable bone discs and screws - Femoral neck discs	Testing against the requirements Bending strength	ASTM F 2502 ASTM F 384
Physical tests	- Skeleton pins and wires - Steinmann skeleton pins - Prosthetic stems	Testing of - Tensile strength - strain Dimension test Endurance test head throat region Endurance test with Torsion load Finite-Element-Analyse Methods of fatigue tests Resistance of femoral head against static and dynamic loads	ISO 5838-1 ISO 5838-2 ISO 7206-6 ISO 7206-4 ASTM F 2996 IMA-PV C/35 ISO 7206-10
Physical tests	Shoulder joint implants	Testing against the requirements Dynamic strength tests Static and dynamic tests regarding loosening behaviour Testing of wear behaviour - Gravimetric - Abrasion - Particle analyse - Contact surface measurement Resistance against static shear load	IMA-PV C/32 ASTM F 2028 IMA-PV C/33.1 IMA-PV C/33.3 IMA-PV C/33.4 (ISO 7206-2, ISO 7207-2, ISO 14242-1, ISO 14242-2, ISO 14243-2) ASTM F1829

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	Ankle joint implants	Testing against the requirements	ASTM F 2665
	diverse material pairings	Testing against the requirements Screening Test Cylinder/ disc	IMA-PV C/36
	Materials for Endoprosthetics - Ultra-High molecular weight polyethylene (UHMWPE)	Testing against requirements Aging	ASTM F 2003
Physical tests	Vertebral column implants - Intervertebral disc - Fixators/pinheads - Blocking implants	Testing against the requirements Expulsion test Static and dynamic tests Specification as well as static and dynamic tests Static and dynamic test from joint elements Static and dynamic strength tests Static and dynamic tests Measuring of subsidence behaviour under static axial compression	IMA-PV C/40 ASTM F 2346 ASTM F 2193 ASTM F 1798 ASTM F 1717 ASTM F 2077 ASTM F 2267
Physical tests	syringes, cannulae and hypodermic medical appliances	Verifying performance requirements - Required force	DIN EN ISO 7886-1

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Visual tests	- surgical implants	Testing against the requirements - Identification, packaging - Testing of foreign metal residues - Visual testing of surface	DIN EN ISO 14630
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Scope at the location Wilhelmine-Reichard-Ring 4

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical tests	Materials for endoprosthetics	Testing against the requirements	
	Cobalt-Chrome-tungsten-Nickel-wrought alloy	Microstructure - Grain size - Tensile strength - 0.2 %-strain limit - Strain	DIN ISO 5832-5
	Cobalt-Nickel-Chrome-Molybdenum wrought alloy	Microstructure (grain size) Mechanical properties - Tensile strength - 0.2 %-strain limit - Strain	DIN ISO 5832-6
	Cobalt-nickel-chrome-Molybdenum-tungsten-iron-wrought alloy	Microstructure (grain size) Mechanical properties - Tensile strength - 0.2 %-strain limit - Percentage strain after fracture - Percentage constriction	DIN ISO 5832-8

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	Cobalt-chrome Molybdenum cast alloy	Mechanical properties <ul style="list-style-type: none"> - Tensile strength - 0.2 %-strain limit - Strain - Constriction 	DIN ISO 5832-4
	Wrought cobalt- chromium-molybdenum alloy	Microstructure (grain size) Mechanical properties <ul style="list-style-type: none"> - Tensile strength - 0.2 %-strain limit - Strain - Percentage constriction 	DIN ISO 5832-12
	Wrought titanium 6- aluminium 7-niobium alloy	Microstructure (grain size) Mechanical properties <ul style="list-style-type: none"> - Tensile strength - 0.2 %-strain limit - Strain - Percentage constriction 	DIN ISO 5832-11
	Wrought titanium 15- molybdenum 5- zirconium 3-aluminium alloy	Microstructure Mechanical properties <ul style="list-style-type: none"> - Tensile strength - 0.2 %-strain limit - Strain - Percentage constriction 	DIN ISO 5832-14
Physical tests	Materials for endoprosthetics	Testing against the requirements	
	Stainless steel	Texture examinations <ul style="list-style-type: none"> - Delta ferrite - Grain size - Degree of purity - Tensile strength 	DIN ISO 5832-1

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
	Forgeable and cold forming cobalt-chrome-nickel-molybdenum iron alloys	Microstructure - Grain size Mechanical properties Non-cold formed condition / cold formed condition - Tensile strength - 0.2 %-strain limit - Strain	DIN ISO 5832-7
	Nitrogenous stainless steel	Microstructure - Grain size - Absence of Delta ferrite Mechanical properties - Tensile strength - Yield/elastic limit - Fracture strain	DIN ISO 5832-9
	Titan-6-Aluminium-4-Vanadium-forging alloy	Microstructure Mechanical properties - Tensile strength - 0.2 %-strain limit - Strain - Constriction - Bending test	DIN ISO 5832-3
Physical tests	Materials for the endoprosthetics Non alloyed titanium	Testing against the requirements Microstructure (grain size)	 DIN ISO 5832-2

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
		Mechanical properties - Tensile strength - 0.2 %-strain limit - Strain - Constriction - Bending test	

Standards³

DIN ISO 5832-1 : 2017-04	Implants for surgery - Metallic materials - Part 1: Wrought stainless steel (ISO 5832-1 : 2016)
DIN ISO 5832-2 : 2012-08	Implants for surgery - Metallic materials - Part 2: Unalloyed titanium (ISO 5832-2 : 1999)
DIN ISO 5832-3 : 2017-03	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy (ISO 5832-3 : 2016)
DIN ISO 5832-4 : 2015-12	Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy (ISO 5832-4 : 2014)
DIN ISO 5832-5 : 2008-04	Implants for surgery - Metallic materials - Part 5: Wrought cobalt-chromium-tungsten-nickel alloy (ISO 5832-5 : 2005)
DIN ISO 5832-6 : 2001-04	Implants for surgery - Metallic materials - Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy (ISO 5832-6 : 1997)
DIN ISO 5832-7 : 2017-09	Implants for surgery - Metallic materials - Part 7: Forgeable and cold-formed cobalt-chromium-nickel-molybdenum-iron alloy (ISO 5832-7 : 2016)
DIN ISO 5832-8 : 2000-08	Implants for surgery - Metallic materials - Part 8: Wrought cobalt-nickel-chromium-molybdenum-tungsten-iron alloy (ISO 5832-8 : 1997)
DIN ISO 5832-9 : 2008-12	Implants for surgery - Metallic materials - Part 9: Wrought high nitrogen stainless steel (ISO 5832-9 : 2007)
DIN ISO 5832-11 : 2015-12	Implants for surgery - Metallic materials - Part 11: Wrought titanium 6-aluminium 7-niobium alloy (ISO 5832-11:2014)
DIN ISO 5832-12 : 2009-04	Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy (ISO 5832-12:2007)

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DIN ISO 5832-14 : 2009-12	Implants for surgery - Metallic materials - Part 14: Wrought titanium 15-molybdenum 5-zirconium 3-aluminium alloy (ISO 5832-14:2007)
ISO 5836 : 1988-12	Implants for surgery; metal bone plates; holes corresponding to screws with asymmetrical thread and spherical under-surface
ISO 5837-1 : 1985-06	Implants for surgery; Intramedullary nailing systems; Part 1 : Intramedullary nails with cloverleaf or V-shaped cross-section
ISO 5838-1 : 2013-03	Implants for surgery - Metallic skeletal pins and wires - Part 1: General requirements
ISO 5838-2 : 1991-01	Implants for surgery; skeletal pins and wires; part 2: Steinmann skeletal pins; dimensions
ISO 5838-3 : 1993-09	Implants for surgery; skeletal pins and wires; part 3: Kirschner skeletal wires
ISO 6475 : 1989-11	Implants for surgery; metal bone screws with asymmetrical thread and spherical under-surface; mechanical requirements and test methods
ISO 7206-2 : 2011-04	Implants for surgery - 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 : 2003-12	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
ISO 7207-2 : 2011-07	Implants for surgery - Components for partial and total knee joint prostheses - Part 2: Articulating surfaces made of metal, ceramic and plastics materials
DIN EN ISO 7886-1 : 2018-07	Sterile hypodermic syringes for single use - Part 1: Syringes for manual use

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ISO 9585 : 1990-12	Implants for surgery; determination of bending strength and stiffness of bone plates
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
DIN EN ISO 14630 : 2013-03	Non-active surgical implants - General requirements (ISO 14630 : 2012)
ISO 14879-1 : 2000-06	Implants for surgery - Total knee-joint prostheses - Part 1: Determination of endurance properties of knee tibial trays
ASTM F 382 : 2017	Standard Specification and Test Method for Metallic Bone Plates
ASTM F 384 : 2017	Standard Specifications and Test Methods for Methods for Metallic Angled Orthopaedic Fracture Fixation Devices
ASTM F 543 : 2017	Standard Specification and Test Methods for Metallic Medical Bone Screws
ASTM F 1044 : 2005(2017)e1	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings
ASTM F1147 : 2005(2017)e1	Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings
ASTM F 1160 : 2014(2017)e1	Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings
ASTM F 1223 : 2014	Standard Test Method for Determination of Total Knee Replacement Constraint
ASTM F 1264 : 2016e1	Standard Specification and Test Methods for Intramedullary Fixation Devices
ASTM F 1717 : 2018	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model

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ASTM F 1798 : 2013	Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
ASTM F 1800 : 2012	Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements
ASTM F 1820 : 2013	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F 1829 : 2017	Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear
ASTM F 1875 : 1998 (2014)	Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface
ASTM F 2003 : 2002 (2015)	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air
ASTM F 2009 : 2000 (2011)	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
ASTM F 2028 : 2017	Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation
ASTM F 2068 : 2015	Standard Specification for Femoral Prostheses – Metallic Implants
ASTM F 2077 : 2017	Test Methods For Intervertebral Body Fusion Devices
ASTM F 2193 : 2018a	Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
ASTM F 2267 : 2004 (2011)	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression
ASTM F 2345 : 2003(2013)	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads
ASTM F 2346 : 2018	Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs
ASTM F 2502 : 2017	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants
ASTM F 2582 : 2014	Standard Test Method for Impingement of Acetabular Prostheses
ASTM F 2665 : 2009 (2014)	Standard Specification for Total Ankle Replacement Prosthesis
ASTM F 2996 : 2013	Standard Practice for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems
ASTM F 3140 : 2017	Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements

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ASTM F 3161 : 2016	Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions
IMA-PV C/25	Hip joint endoprosthesis - dynamic strength test - ceramic hip joint ball and socket
IMA-PV C/29	Coupling ball / plate wear test with oscillating stress
IMA-PV C/30	Determination of the contact surface and the pressure distribution of articulating surfaces by means of pressure measuring films
IMA-PV C/31	Knee joint implant strength tests to investigate the fatigue behavior of femoral components
IMA-PV C/32	Shoulder joint endoprosthesis-Dynamic strength test shoulder shaft
IMA-PV C/33.1	Shoulder joint endoprosthesis wear test - anatomical shoulder
IMA-PV C/33.3	Shoulder joint implant wear trial - Shoulder with edge loading
IMA-PV C/33.4	Shoulder joint endoprosthesis wear test - inverse shoulder
IMA-PV C/35	Methods for fatigue tests to confirm a required fatigue strength
IMA-PV C/36	Wear Test Screening Test Cylinder / Plate
IMA-PV C/38	Knee joint implant strength tests to investigate the fatigue behavior of tibial plateaus with long shanks
IMA-PV C/40	Spinal implant expulsion test

Abbreviations used:

ASTM	American Society for Testing and Materials
DIN	Deutsches Institut für Normung e.V.
EN	Europäische Norm
ISO	International Organisation for Standardisation
IMA-PV	In house method of the IMA Materialforschung und Anwendungstechnik GmbH

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

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

³ For the transition periods, see the list of harmonized standards on the homepage of the EU.

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