Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18721-01-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **09.06.2021**

Date of issue: 21.07.2021

Holder of certificate:

CeramTec GmbH
CeramTec-Platz 1-9, 73207 Plochingen

at location:

Zentrale Labore LAB
CeramTec-Platz 1-9, 73207 Plochingen

Field: Medical devices

Testing fields/test items: Physical tests of implants

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation may be found respectively in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH https://www.dakks.de/en/content/accredited-bodies-dakks.

Abbreviations used: see last page

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical tests	Hip joints implants	Determination of compliance to requirements	
		Resistance of femoral heads against static and dynamic loads	ISO 7206-10
		Resistance against torsional loads	ISO 7206-13
		Determination of fixation force for disassembly of modular acetabular devices	ASTM F1820
		Strength of modular joints	ASTM F2009 ASTM F2345
		Impact resistance of hip joint protheses - quasi static	ISO 11491
		Deformation tests for acetabular shells	ISO 7206-12
	Materials for the endoprostheses - Aluminium oxide (alumina) ceramic	Determination of compliance to requirements - thickness - chemical composition - microstructure - strength test - elasticity modulus - fracture resistance - hardness - cyclical fatigue	ISO 6474-1
	Zirconia reinforced alumina ceramic	- thickness - chemical composition - microstructure - strength test - fracture resistance - hardness - elasticity modulus - accelerated aging	ISO 6474-2

Physical tests	- yttria-stabilised tetragonal zirconia (Y-TZP ceramic)	- thickness - chemical composition - microstructure (incl. monoclinical phase parts) - strength test - elasticity modulus - hardness - cyclical fatigue - accelerated aging	DIN EN ISO 13356
	Dental implants	Determination of compliance to requirements dynamic loading test	DIN EN ISO 14801

standards:

DIN EN ISO 13356:2016-02	Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015); German version EN ISO 13356:2015
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 6474-1:2019-03	Implants for surgery - Ceramic materials - Part 1: Ceramic materials based on high purity alumina
ISO 6474-2:2019-03	Implants for surgery - Ceramic materials - Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement
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
ISO 11491:2017-07	Implants for surgery - Determination of impact resistance of ceramic femoral heads for hip joint prostheses
ASTM F1820-13	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
ASTM F2009-20	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses
ASTM F2345-03 (2013)	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads

Abbreviations used:

ASTM	American Society for Testing and Materials
DIN	German Institute for Standardisation
EN	European Standard
ISO	International Organisation for Standardisation
IEC	International Electronical Commission

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