

Deutsche Akkreditierungsstelle GmbH

Entrusted according to Section 8 subsection 1 AkkStelleG in connection with Section 1 subsection 1 AkkStelleGBV

Signatory to the Multilateral Agreements of EA, ILAC and IAF for Mutual Recognition

Accreditation



The Deutsche Akkreditierungsstelle GmbH attests that the testing laboratory

CeramTec GmbH
CeramTec-Platz 1-9, 73207 Plochingen

at location:

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

is competent under the terms of DIN EN ISO/IEC 17025:2018 to carry out tests in the following fields:

Field: Medical devices

Testing fields/test items: Physical tests of implants

The accreditation certificate shall only apply in connection with the notice of accreditation of 09.06.2021 with the accreditation number D-PL-18721-01. It comprises the cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

Registration number of the certificate: **D-PL-18721-01-02**

Frankfurt am Main,
09.06.2021

Dipl.-Ing. (FH) Ralf Egner
Head of Division

Translation issued:
21.07.2021



Head of Division

*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>.*

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

See notes overleaf.

Deutsche Akkreditierungsstelle GmbH

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The publication of extracts of the accreditation certificate is subject to the prior written approval by Deutsche Akkreditierungsstelle GmbH (DAkkS). Exempted is the unchanged form of separate disseminations of the cover sheet by the conformity assessment body mentioned overleaf.

No impression shall be made that the accreditation also extends to fields beyond the scope of accreditation attested by DAkkS.

The accreditation was granted pursuant to the Act on the Accreditation Body (AkkStelleG) of 31 July 2009 (Federal Law Gazette I p. 2625) and the Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (Official Journal of the European Union L 218 of 9 July 2008, p. 30). DAkkS is a signatory to the Multilateral Agreements for Mutual Recognition of the European co-operation for Accreditation (EA), International Accreditation Forum (IAF) and International Laboratory Accreditation Cooperation (ILAC). The signatories to these agreements recognise each other's accreditations.

The up-to-date state of membership can be retrieved from the following websites:

EA: www.european-accreditation.org

ILAC: www.ilac.org

IAF: www.iaf.nu

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-18721-01-02 according to DIN EN ISO/IEC 17025:2018¹

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.

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Abbreviations used: see last page

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

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 Resistance against torsional loads Determination of fixation force for disassembly of modular acetabular devices Strength of modular joints Impact resistance of hip joint prostheses - quasi static Deformation tests for acetabular shells	ISO 7206-10 ISO 7206-13 ASTM F1820 ASTM F2009 ASTM F2345 ISO 11491 ISO 7206-12
	Materials for the endoprotheses - Aluminium oxide (alumina) ceramic Zirconia reinforced alumina ceramic	Determination of compliance to requirements - thickness - chemical composition - microstructure - strength test - elasticity modulus - fracture resistance - hardness - cyclical fatigue - thickness - chemical composition - microstructure - strength test - fracture resistance - hardness - elasticity modulus - accelerated aging	ISO 6474-1 ISO 6474-2

Annex to the accreditation certificate D-PL-18721-01-02

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 Electrotechnical Commission

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