

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-17042-01-00 according to DIN EN ISO/IEC 17025:2018¹

Period of validity: 20.02.2019 to 04.10.2022 Date of issue: 20.02.2019

Holder of certificate:

CPM Diagnostics GmbH
Im Rott 5, 69493 Hirschberg

Field: Medical devices

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

Abbreviations used: see last page

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical testing	Dental implants	Dynamic fatigue test	DIN EN ISO 14801
	Dental implants and accessories - dental implants - skeleton implants	Determination of properties - surface mapping - Roughness determination	AA-Diagnostics_02 AA-Diagnostics_05
	Dental implants and accessories - dental implants - skeleton implants	Determination of properties - surface mapping - Roughness determination	AA-Diagnostics_02 AA-Diagnostics_05
Physical-chemical testing	Dental implants and accessories	- Determination of properties - Material composition	AA-Diagnostics_03 AA-Diagnostics_04

Regulations:

DIN EN ISO 14801:2017-03	Dentistry – Implants – Dynamic fatigue test for endosseous dental implants
AA-Diagnostics_02	Display of specimen surfaces via secondary electrons (SE) – SEM scanning electron microscope method
AA-Diagnostics_03	Recording of spectra of compact specimens, powders and separates - EDX
AA-Diagnostics_04	Standardless quantitative evaluation of EDX spectra
AA-Diagnostics_05	Roughness determination with a confocal microscope

Abbreviations used:

AA-Diagnostics	Internal work instruction of CPM Diagnostics
DIN	Deutsches Institut für Normung (German institute for Standardization)
EN	Europäische Norm (European standard)
ISO	International Organisation for Standardization

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