

# Deutsche Akkreditierungsstelle GmbH

## Annex to the Accreditation Certificate D-PL-17042-01-00 according to DIN EN ISO/IEC 17025:2018<sup>1</sup>

**Valid from:**

Date of issue:

Holder of certificate:

**CPM Diagnostics GmbH**  
**Im Rott 5, 69493 Hirschberg**

**Field:** Medical devices

**Testing fields/test items:** Physical tests of implants and accessories

*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 can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at <https://www.dakks.de/en/content/accredited-bodies-dakks>.*

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.**

**Annex to the accreditation certificate D-PL-17042-01-0000**

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical testing	Dental implants	Determination of properties - Dynamic fatigue test	DIN EN ISO 14801
	Implants and accessories - Dental implants - skeleton implants - Spinal implant	Determination of properties - surface mapping  - Roughness determination	ASTM E1508IPV-Diagnostics_01  DIN EN ISO 25178-606 IPV-Diagnostics_05
	Implants and accessories - Dental implants - skeleton implants - Spinal implant	Determination of properties - Material composition	ASTM E1508 IPV-Diagnostics_02 IPV-Diagnostics_03
	Implants, accessories, injection moulding parts - Dental implants - skeleton implants	Determination of properties - Non-destructive material testing using computed tomography	DIN EN ISO 15708-3 IPV-Diagnostics_04 Referred document: DIN EN ISO 15708-1 DIN EN ISO 15708-2 DIN EN ISO 15708-4

**Regulations:**

DIN EN ISO 14801: 2017-03	Dentistry - Implants - Dynamic loading test for endosseous dental implants (ISO 14801:2016); German version EN ISO 14801:2016
DIN EN ISO 15708-1: 2019-09	Non-destructive testing - Radiation methods for computed tomography - Part 1: Terminology (ISO 15708-1:2017); German version EN ISO 15708-1:2019
DIN EN ISO 15708-2: 2019-09	Non-destructive testing - Radiation methods for computed tomography - Part 2: Principles, equipment and samples (ISO 15708-2:2017); German version EN ISO 15708-2:2019

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DIN EN ISO 15708-3: 2019-09	Non-destructive testing - Radiation methods for computed tomography - Part 3: Operation and interpretation (ISO 15708-3:2017); German version EN ISO 15708-3:2019
DIN EN ISO 15708-4: 2019-09	Non-destructive testing - Radiation methods for computed tomography - Part 4: Qualification (ISO 15708-4:2017); German version EN ISO 15708-4:2019
DIN EN ISO 25178-606: 2016-12	Geometrical product specification (GPS) - Surface texture: Areal - Part 606: Nominal characteristics of non-contact (focus variation) instruments (ISO 25178-606:2015); German version EN ISO 25178-606:2015
ASTM E1508-12a (2019)	Standard Guide for Quantitative Analysis by Energy-Dispersive Spectroscopy
IPV-Diagnostics_01 (24.03.2022)	Display of specimen surfaces via secondary electrons (SE) – SEM scanning electron microscope method
IPV-Diagnostics_02 (24.03.2022)	Recording of spectra of compact specimens, powders and separates - EDX
IPV-Diagnostics_03 (24.03.2022)	Standardless quantitative evaluation of EDX spectra
IPV-Diagnostics_04 (24.03.2022)	Creation of radiographic data - industrial computed tomography
IPV-Diagnostics_05 ((24.03.2022)	Roughness determination with a confocal microscope

**Abbreviations used:**

ASTM	American Society for Testing and Materials
DIN	Deutsches Institut für Normung (German institute for Standardization)
EN	Europäische Norm (European standard)
ISO	International Organisation for Standardization
IPV-Diagnostics	Internal work instruction of CPM Diagnostics

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