Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-11140-07-02 according to DIN EN ISO/IEC 17025:2018

Valid from: **26.10.2022**

Date of issue: 26.10.2022

This annex is a part of the accreditation certificate D-PL-11140-07-00.

Holder of partial accreditation certificate:

Fraunhofer Gesellschaft zur Förderung der angewandten Forschung eingetragener Verein
Hansastraße 27 c, 80686 München

with its testing laboratory

Fraunhofer Institut für Produktionstechnik und Automatisierung IPA
Nobelstraße 12, 70569 Stuttgart

The testing laboratory meets the minimal requirements of DIN EN ISO/IEC 17025:2018 and, if applicable, additional legal and normative requirements, including those in relevant sectoral schemes, in order to carry out the conformity assessment activities listed below.
The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and confirm generally with the principles of DIN EN ISO 9001.

Field:	Medical devices
Testing fields/test items:	Biological tests of medical devices; environmental monitoring

This certificate annex is only valid together with the written accreditation certificate and 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.

Testing field	**Test item Device(category)**	**Type of testing Test**	**Regulation Testing method**
Biological testing	Medical devices	Cytotoxicity test	DIN EN ISO 10993-5 SAA IVT 01-0
		Activity of metabolism after contact with extracts or direct contact (MTS-test)	applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
Environmental monitoring in the process of production and testing of cleanliness of the products according to DIN EN ISO 13485:2021[1], Par. 6.4 and Par. 7.5			
Physical testing	Medical devices, Surfaces	Testing of particulate impurities (Light microscopy)	VDI 2083, Part 21

Regulations:

DIN EN ISO 10993-1 2021-05	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
DIN EN ISO 10993-5 2009-10	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
DIN EN ISO 10993-12 2021-08	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
VDI 2083 Part 21 2019-10	Cleanroom technology - Cleanliness of medical devices in the manufacturing process B3.3, Particulate impurities, Light microscopy (automated with image processing)
SAA IVT 01-0 Rev. 0	In-vitro-Zytotoxizität nach DIN EN ISO 10993-5

abbreviations used:

DIN	German Institute for Standardization
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
SAA IVT XXX	Standard operating procedure of Fraunhofer IPA
VDI	Association of German Engineers *(German: Verein Deutscher Ingenieure)*

[1] DIN EN ISO 13485:2021: Medical devices - Quality management systems - Requirements for regulatory purposes