

Deutsche Akkreditierungsstelle

Annex to the Partial Accreditation Certificate D-PL-11140-07-03 according to DIN EN ISO/IEC 17025:2018

Valid from: 02.05.2024

Date of issue: 02.05.2024

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 the location

**Fraunhofer-Gesellschaft zur Förderung der angewandten Forschung
eingetragener Verein
Fraunhofer-Institut für Produktionstechnik und Automatisierung IPA
Nobelstraße 12, 70569 Stuttgart**

The testing laboratory meets the requirements of DIN EN ISO/IEC 17025:2018 to carry out the conformity assessment activities listed in this annex. The testing laboratory meets additional legal and normative requirements, if applicable, including those in relevant sectoral schemes, provided that these are explicitly confirmed below.

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories and they conform to the principles of DIN EN ISO 9001.

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 in the fields of:

Biological testing In-vitro Test Systems on research and industry products

Within the given testing field, the testing laboratory is permitted, without being required to inform and obtain prior approval from DAkkS, the free choice of standard or equivalent testing methods. The listed testing methods are exemplary. The testing laboratory maintains a current list of all testing methods within the flexible scope of accreditation.

1 Cytotoxicity test

| Type of test | Measured variables / test parameters | Test methods (characteristic) |
|-------------------|---|-------------------------------|
| Cytotoxicity test | Cytotoxicity based on cell vitality (here: <i>not for medicine products</i>) | DIN EN ISO 10993-5 |

2 Irritation and corrosion tests on reconstructed human tissue models

| Type of test | Measured variables / test parameters | Test methods (characteristic) |
|---|--|--|
| Irritation and corrosion tests on reconstructed human tissue models | Reversible (irritation) and irreversible (corrosion) impairment of tissue vitality (here: <i>reconstructed human epidermis</i>) | OECD Test Guideline 431 OECD Test Guideline 439 |

Abbreviations used:

- DIN German institute for standardization
- EN European Standard
- IEC International Electrotechnical Commission
- ISO International Organization for Standardisation
- OECD Organization for Economic Cooperation and Development