DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that

NAMSA Laboratory Services
GmbH Industrie Center
Obernburg
63784 Obernburg am Main

operates a testing laboratory that fulfills the requirements according to DIN EN ISO/IEC 17025:2018 for those conformity assessment activities specified in detail in the annex listed below. This includes additional existing legal and normative requirements for the testing laboratory including those in relevant sectoral schemes, provided that these are explicitly confirmed in the annex listed below.

D-PL-21154-01-01 **Valid from: 19.03.2026**

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 accreditation was issued in accordance with Art. 5 Para. 1 Sentence 2 of Regulation (EC) 765/2008, after an accreditation procedure was carried out in compliance with the minimum requirements of DIN EN ISO/IEC 17011 and on the basis of a review and decision of the appointed accreditation committees.

This accreditation certificate only applies in connection with the notice of 19.03.2026. It consists of this cover sheet, the reverse side of the cover sheet and the corresponding annex .

Registration number of the accreditation certificate: **D-PL-21154-01-00**

Berlin, 19.03.2026 Dipl. Biol. Andrea Gabler
Head of Technical Unit

Translation issued: 19.03.2026

This accreditation certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS). It is digitally sealed and valid without signature. It reflects the status as indicated by the date of issue. The current status of any valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

Office Berlin
Spittelmarkt 10
10117 Berlin

The Deutsche Akkreditierungsstelle GmbH (DAkkS) is the entrusted national accreditation body of the Federal Republic of Germany according to § 8 section 1 AkkStelleG in conjunction with § 1 section 1 AkkStelleGBV. DAkkS is designated as the national accreditation authority by Germany according to Art. 4 Para. 4 of Regulation (EC) 765/2008 and clause 4.7 of DIN EN ISO/IEC 17000.

Pursuant to Art. 11 section 2 of Regulation (EC) 765/2008, the accreditation certificate shall be recognised as equivalent by the national authorities within the scope of this Regulation as well as by the WTO member states that have committed themselves in bilateral or multilateral mutual agreements to recognise the certificates of accreditation bodies that are members of ILAC or IAF as equivalent.

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 Co-operation (ILAC).

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

Annex to the Accreditation Certificate D-PL-21154-01-01 according to DIN EN ISO/IEC 17025:2018

Valid from: **19.03.2026**

Date of issue: 19.03.2026

This annex is part of the Accreditation Certificate D-PL-21154-01-00.

Holder of the Accreditation Certificate:

NAMSA Laboratory Services GmbH
Industrie Center Obernburg
63784 Obernburg am Main

with the location

NAMSA Laboratory Services GmbH
Industrie Center Obernburg
63784 Obernburg am Main

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.

Chemical testing of medical devices

outside of a recognition according to § 18 Medical Device Law Implementation Act.

This annex to the certificate was issued by the Deutsche Akkreditierungsstelle GmbH (DAkkS) and is digitally sealed.
This annex to the certificate 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 valid and surveyed accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH (www.dakks.de).

Testing area	Test item Device (category)	Type of testing Test	Regulation Testing method
Chemical Testing	Medical devices - Polymers	Tests within the scope of chemical characterization *Qualitative and Quantitative* - Chemical Structure	DIN EN ISO 10993-18 TM_01002 TM_01010
		- Surface Composition	TM_00227 TM_00228 TM_01001 TM_01004 TM_01011 Applicable: USP <621>
	- Metals and Alloys	*Qualitative and Quantitative* - Chemical Composition	TM_01003
	- Ceramics	*Qualitative and Quantitative* - Characterization of the extractability of extractable substances	TM_01003 TM_01008
	- Natural Macromolecules	- Chemical Structure	TM_01004 Applicable: DIN EN ISO 10933-1 DIN EN ISO 10993-12 USP<621> USP<197>

List of regulations/test methods:

DIN EN ISO 10993-1: 2021-05	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)
DIN EN ISO 10993-12:2021-08	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)
DIN EN ISO 10993-18:2021-03	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)
TM_ 00227[1]	LC-UV-MS screening of non-volatile organic compounds with UV-based quantification
TM_ 00228[1]	LC-UV-MS screening of non-volatile organic compounds with UV and MS based quantification
TM_01001[1]	Ultra Performance Liquid Chromatography-Ultraviolet-Mass Spectrometry Non-Volatile Screen (UPLC-UV-MS)
TM_01002[2]	Determination of Extractable Volatile Organic Compounds by Headspace Gas Chromatography-Mass Spectrometry (HSS-GC-MS)
TM_01003[2]	Determination of Extractable Elements by Inductively Coupled Plasma-Mass Spectroscopy (ICP-MS)
TM_01004[2]	Infrared Spectroscopy (FTIR)
TM_01008[1]	Exhaustive Extraction
TM_01010[1]	Determination of Extractable Semi-Volatile Organic Compounds by Gas Chromatography-Mass Spectrometry (GC-MS)
TM_01011[1]	Quantitative and semi-quantitative determination of non-volatile organic compounds using ultra-high performance liquid chromatography-UV photometry-mass spectrometry (UPLC-UV-MS)
USP 40 <197>	Spectrophotometric Identification Tests
USP 40 <621>	Chromatography

Abbreviations used:

DIN	Deutsches Institut für Normung e.V. – German institute for standardization
EN	Europäische Norm – European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardisation
TM	Test Method
USP	United States Pharmacopeia