DAkkS
Deutsche
Akkreditierungsstelle

Accreditation

The Deutsche Akkreditierungsstelle attests with this **Accreditation Certificate** that the testing laboratory

NAMSA Laboratory Services
GmbH Industrie Center
Obernburg
63784 Obernburg am Main

meets the requirements according to DIN EN ISO/IEC 17025:2018 for the conformity assessment activities listed in the annex to this certificate. This includes additional existing legal and normative requirements for the testing laboratory, including those in relevant sectoral schemes, provided they are explicitly confirmed in the annex to this certificate.

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 notices of 15.07.2024 with accreditation number D-PL-21154-01.
It consists of this cover sheet, the reverse side of the cover sheet and the following annex with a total of 4 pages.

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

Berlin, 28.10.2024
Andrea Gabler
Head of Technical Unit

Translation issued:
28.10.2024
Andrea Gabler
Head of Technical Unit

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 (www.dakks.de).

See notes overleaf

Deutsche Akkreditierungsstelle GmbH

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60327 Frankfurt am Main

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38116 Braunschweig

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 Partial Accreditation Certificate D-PL-21154-01-00 according to DIN EN ISO/IEC 17025:2018

Valid from: **15.07.2024**

Date of issue: 28.10.2024

Holder of partial 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 recognition in accordance with Section 18 of the Medical Devices Law Implementation Act.

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 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 GNQS-TM-00002 NFLS-TM-00010
		- Surface Composition	GNQS-TM-00001 GNQS-TM-00004 NFLS-TM-00011 Applicable: USP <621>
	- Metals and Alloys	*Qualitative und quantitative* - Chemical Composition	GNQS-TM-00003
	- Ceramics	*Qualitative und quantitative* - Characterization of the extractability of extractable substances *Qualitative*	NFLS-TM-00008 GNQS-TM-00003
	- Natural Macromolecules	- Chemical Structure	GNQS-TM-00004 Applicable: DIN EN ISO 10933-1 DIN EN ISO 10993-12 USP<621> USP<197> FDA Guidance use of ISO 10993-1

Regulations:

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)*
FDA Guideline use of ISO 10993-1: 2016-06	*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff*
*GNQS-TM-00001 Rev. B/TM_01001 Rev. 1**	*Determination of Extractable Non-Volatile Organic Compounds (UPLC-UV-MS)*
*GNQS-TM-00002 Rev. D/TM_01002 Rev. 1**	*Determination of Extractable Volatile Organic Compounds (GCMS)*
*GNQS-TM-00003 Rev. B/TM_01003 Rev. 1**	*Determination of Extractable Elements by Inductively Coupled Plasma-Mass Spectroscopy (ICP-MS)*
*GNQS-TM-00004 Rev. C/TM_01004 Rev. 1**	*Infrared Analysis (FTIR)*
*NFLS-TM-00008 Rev. E/TM_01008 Rev.1**	*Exhaustive Extraction*
*NFLS-TM-00010 Rev. E/TM_01010 Rev. 1**	*Determination of Extractable Semi-Volatile Organic Compounds by Gas Chromatography-Mass Spectrometry (GC-MS)*
*NFLS-TM-00011 Rev. A/TM_01001 Rev. 1**	*Quantitative and Semi-Quantitative Determination of Non-Volatile Organic Compounds by 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	German Institute for Standardization
EN	European Standard
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
FDA	Food and Drug Administration
USP	United States Pharmacopeia
NFLS	Standard Operating Procedure of NAMSA Laboratory Services GmbH
GNQS	Global Standard Operating Procedure NAMSA (Global NAMSA Quality Systems)