Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-21154-01-00 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: 27.07.2022

Date of issue: 27.07.2022

Holder of certificate:

NAMSA Laboratory Services GmbH
Industrie Center Obernburg, 63784 Obernburg am Main

Field: Medical devices

Testing fields/test items: Chemical testing of Medical devices

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH. https://www.dakks.de/en/content/accredited-bodies-dakks

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Chemical Testing	Medical Devices	Tests within the scope of chemical characterization	DIN EN ISO 10993-18
	- Polymers	*Qualitative and Quantitative*	
		- Chemical Structure	USP <621> GNQS-TM-00002 NFLS-TM-00010
		- Surface Composition	GNQS-TM-00001 GNQS-TM-00004
	- Metals and Alloys	*Qualitative and Quantitative*	
		- Chemical Composition	GNQS-TM-00003
	- Ceramics	*Qualitative and Quantitative*	
		- Characterization of extractability of extractable substances	NFLS-TM-00008 GNQS-TM-00003
	- Natural Macromolecules	*Qualitative*	
		- 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 10933-1

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Regulations[2]

DIN EN ISO 10993-1 : 2021-05	Biologische Beurteilung von Medizinprodukten - Teil 1: Beurteilung und Prüfungen im Rahmen eines Risikomanagementsystems (ISO 10993-1:2018, einschließlich korrigierte Fassung 2018-10)
DIN EN ISO 10993-12 : 2021-08	Biologische Beurteilung von Medizinprodukten - Teil 12: Probenvorbereitung und Referenzmaterialien (ISO 10993-12:2021)
DIN EN ISO 10993-18 : 2021-03	Biologische Beurteilung von Medizinprodukten - Teil 18: Chemische Charakterisierung von Werkstoffen für Medizinprodukte im Rahmen eines Risikomanagementsystems (ISO 10993-18:2020)
FDA Guidance 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.A	Bestimmung extrahierbarer, nichtflüchtiger organischer Substanzen (UPLC-MS)
GNQS-TM-00002 Rev. C	Bestimmung extrahierbarer, flüchtiger organischer Substanzen (GC-MS)
GNQS-TM-00004 Rev. C	Infrarotanalyse (FTIR)
GNQS-TM-00003 Rev. A	Bestimmung extrahierbarer Elemente mittels induktiver gekoppelter Plasma/Massenspektroskopie (ICP-MS)
NFLS-TM-00008 Rev. C	Erschöpfende Extraktion
NFLS-TM-00010 Rev. B	Bestimmung von extrahierbaren halbflüchtigen organischen Verbindungen mittels Gaschromatographie_Massenspektrometrie (GC-MS)
USP 40 <621>	Chromatography
USP 40 <197>	Spectrophotometric Identification Tests

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Abbreviations used: see last page

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Abbreviations used:

DIN	Deutsches Institut für Normung e. V.
EN	Europäische Norm
ISO	International Organization for Standardization
FDA	Food and Drug Administration
USP	United States Pharmacopeia
NFLS	Standardarbeitsanweisung der NAMSA Laboratory Services GmbH
GNQS	Globale Standardarbeitsanweisung NAMSA (Global NAMSA Quality Systems)

[1] DIN EN ISO/IEC 17025:2018: General requirements for the competence of testing and calibration laboratories

[2] For the transition periods, see the list of harmonized standards on the homepage of the EU.

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