

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-11118-01-02 according to DIN EN ISO/IEC 17025¹:2005

Period of validity: 25.01.2018 to 24.01.2023

Date of issue: 25.01.2018

Holder of certificate:

Ostthüringische Materialprüfgesellschaft für Textil und Kunststoffe mbH
Breitscheidstraße 97, 07407 Rudolstadt

field: medical devices

test fields/test specimen: biological and microbiological-hygienical tests
of medical devices

abbreviations used: see last page

Tests in the fields:

test field	test specimen product (category)	type of test test	standards, test methods
biological tests	medical devices	biological evaluation of medical devices - Part 5: Tests for <i>in vitro</i> cytotoxicity	DIN EN ISO 10993-5 SOP 4.5.503 Bio applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		<i>In vitro</i> skin corrosion: -reconstructed human epidermis (RHE) test method	OECD Guideline 431 SOP 4.5.528 applicable: DIN EN ISO 10993-1

test field	test specimen product (category)	type of test test	standards, test methods
		<i>In vitro</i> skin irritation: - reconstructed human epidermis (RHE) test method	OECD Guideline 439 SOP 4.5.529 SOP 4.5.531 applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-10 DIN EN ISO 10993-12
microbiological-hygienical tests	medical devices	measurement / determination of antibacterial activity	ISO 22196 SOP 4.5.505 Bio DIN EN ISO 20645 SOP 4.5.530 Bio DIN EN ISO 20743 SOP 4.5.504 Bio

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standards²

DIN EN ISO 10993-1 2010-04	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 <i>in vitro</i> cytotoxicity
DIN EN ISO 10993-10 2014-10	biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
DIN EN ISO 10993-12 2012-10	biological evaluation of medical devices - Part 12: Sample preparation and reference materials
DIN EN ISO 20645 2005-02	Determination of antibacterial activity - Agar diffusion plate test
DIN EN ISO 20743 2013-12	Textiles- Determination of antibacterial activity of textile products
ISO 22196 2011-08	Measurement of antibacterial activity on plastics and other non-porous surfaces
OECD Guidelines for the Testing of Chemicals 431: 2014-09	In vitro skin corrosion: reconstructed human epidermis (RhE) test method
OECD Guidelines for the Testing of Chemicals 439: 2015-07	In vitro skin irritation: reconstructed human epidermis (RhE) test method
SOP 4.5.503 Bio	procedure for test for <i>in vitro</i> cytotoxicity
SOP 4.5.504 Bio	determination of antibacterial activity of textiles according to absorption method
SOP 4.5.505 Bio	determination of antibacterial activity of plastics
SOP 4.5.528 Bio	<i>In vitro</i> skin corrosion test on human 3D - epidermis models
SOP 4.5.529 Bio	<i>In vitro</i> skin irritation test on human 3D - epidermis models
SOP 4.5.530 Bio	Agar diffusion plate test
SOP 4.5.531 Bio	<i>In vitro</i> skin irritation test on human 3D - epidermis models of extracts of three-dimensional products

abbreviations used:

DIN	German institute of standardisation
EN	European standard
ISO	International organisation for standardisation
SOP	standard operating procedure (sop) of OMPG
OECD	Organisation for Economic Co-operation and Development

¹ DIN EN ISO/IEC 17025 : 2005-08 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.