Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13096-01-02 according to DIN EN ISO/IEC 17025:2018[1]

Valid from: **03.10.2020**

Date of issue: 03.10.2020

Holder of certificate:

BIOSERV Analytik und Medizinprodukte GmbH
Dr.-Lorenz-Weg 1, 18059 Rostock

Tests in the fields:

Field:	Medical devices and the Directive 93/42/EEC[2] and 90/385/EEC[3]
Testing fields/test items:	biological, chemical, microbiological-hygienic and physical testing of medical devices; environmental monitoring

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

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

Abbreviations used: see last page

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Biological testing	Medical devices	Testing for genotoxicity, carcinogenicity and reproductive toxicity	DIN EN ISO 10993-3
		in vitro-genotoxicity tests	
		- In vitro Bacterial Reverse Mutation Test	OECD Guideline 471 4-09-SOP-11-132 4-09-SOP-11-171
		- In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene	OECD Guideline 490 4-09-SOP-11-153
		- Micronucleus-Assay	OECD-Guideline 487 4-09-SOP-11-164
		in vivo-genotoxicity tests Carcinogenicity Studies	OECD Guidelines 451, 453
		reproductive and developmental toxicity tests	OECD Guidelines 414, 416, 421, 422, 443
		- Prenatal Developmental Toxicity Study	
		- Two-Generation Reproduction Toxicity	
		- Reproduction/Developmental Toxicity Screening Test	
		- Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test	
		- Extended One-Generation Reproductive Toxicity Study	
			Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-2 DIN EN ISO 10993-12

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Biological testing	Medical devices	Tests in the context of interaction with blood	DIN EN ISO 10993-4
		- Examination of hemolysis for assessment of hemolytic properties (material-conditioned)	4-09-SOP-11-185
		- Thrombosis • Coagulation • Activation of thrombocytes • complement activation • Haematology	4-09-SOP-11-134 4-09-SOP-11-191 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12 ASTM F756
		Testing for in-vitro cytotoxicity	DIN EN ISO 10993-5 USP <87>
		- Examination of Cytotoxicity , Test on extracts, Liquids, Test by direct contact or by indirect contact (agar diffusion test)	4-09-SOP-03-022 4-09-SOP-03-024 4-09-SOP-03-025 4-09-SOP-03-026 4-09-SOP-03-030 4-09-SOP-03-031 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Test for local effects after implantation Implantation Evaluation	DIN EN ISO 10993-6 USP <88> 4-09-SOP-11-139 4-09-SOP-11-156 4-09-SOP-11-157 4-09-SOP-11-188 Applicable:: DIN EN ISO 10993-1 DIN EN ISO 10993-12

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Biological testing	Medical devices	Testing for irritation and skin sensitization	DIN EN ISO 10993-10 OECD Guidelines 404, 405, 406, USP <88>, USP <1184>
		- in-vivo animal irritation test	4-09-SOP-11-128
		- in-vivo animal intracutaneous reactivity test	4-09-SOP-11-122 4-09-SOP-11-186
		- in-vivo oral mucosa irritation test	4-09-SOP-11-137
		- in-vivo ocular irritation test	4-09-SOP-11-133
		- in-vivo penile irritation test	4-09-SOP-11-170
		- in-vivo rectal irritation test	4-09-SOP-11-167
		- in-vivo vaginal irritation test	4-09-SOP-11-180
		- Murine Local Lymph Node Assay (LLNA)	4-09-SOP-11-160
		- Guinea pig maximization test (Magnusson & Kligman)	4-09-SOP-11-147
		- Closed-patch test (Buehler test)	4-09-SOP-11-123
		In vitro test for irritation	
		- skin	OECD Guideline 439 4-09-SOP-20-129
		- eye	OECD Guideline 492 4-09-SOP-20-196 4-09-SOP-20-197 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Biological testing	Medical devices	Tests for systemic toxicity - Acute systemic toxicity - Repeated exposure systemic toxicity (subacute, subchronic and chronic systemic toxicity)	DIN EN ISO 10993-11 OECD Guidelines 401, 402, 403, 407, 408, 410-413, 420, 423, 425, 433, 452, 453 USP <88> 4-09-SOP-11-124 4-09-SOP-11-165 4-09-SOP-11-166 4-09-SOP-11-187 4-09-SOP-11-135 4-09-SOP-11-136 4-09-SOP-11-162 Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
		Pyrogens (rabbit)	Ph. Eur. 2.6.8 4-09-SOP-11-126
		Monocyte-activation test	Ph. Eur. 2.6.30 4-09-SOP-11-195
Chemical testing	Medical devices, biomaterials - Ceramics - Polymers	Tests within the scope of chemical characterization Qualitative and/or quantitative data - Anions - Characterization of the extractability of extractable substances	DIN EN ISO 10993-18 DIN EN ISO 8536-4 ASTM F2212 4-09-SOP-02-134 4-09-SOP-02-160 4-09-SOP-02-161 4-09-SOP-02-172 4-09-SOP-11-172 4-09-SOP-11-184

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Chemical testing	Medical devices, biomaterials - Ceramics - Polymers	Tests within the scope of chemical characterization Qualitative and/or quantitative data - Characterization of copolymers - Chemical structure - Chemical composition, trace substances - Configuration of the polymer chains - Microstructure - Monomer residues - additives, process residues, trace substances or impurities	Applicable: DIN EN ISO 10993-1 DIN EN ISO 10993-12
Chemical testing	Surgical and dental hand instruments/ metallic materials (dentistry)	Corrosion tests and tarnish test	DIN EN ISO 13402 DIN EN ISO 10271 ASTM F1089 4-09-SOP-02-128 4-09-SOP-02-148 4-09-SOP-02-149 Applicable: DIN EN ISO 22674 DIN EN ISO 10993-1 DIN EN ISO 10993-12
	Dental ceramic materials	Determination of the chemical solubility	DIN EN ISO 6872 4-09-SOP-02-133

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Chemical testing	Medical devices	Testing for purity and identity	Ph. Eur. 2.2.1 Ph. Eur. 2.2.2 Ph. Eur. 2.2.25 Ph. Eur. 2.4.8 Ph. Eur. 3.1 Ph. Eur. 3.2. Ph. Eur. 3.3. Ph. Eur. Monograph 1317 Ph. Eur. Monograph 1472 4-09-SOP-02-115 4-09-SOP-02-116 4-09-SOP-02-117 4-09-SOP-02-118 4-09-SOP-02-119 4-09-SOP-02-121 4-09-SOP-02-122 4-09-SOP-02-123 4-09-SOP-02-127 4-09-SOP-02-131 4-09-SOP-02-140 4-09-SOP-02-168
Chemical testing	Medical devices / solutions	Test for determination - Density - Osmolality - pH value or redox potential	 Ph. Eur. 2.2.5 4-09-SOP-02-138 Ph. Eur. 2.2.35 4-09-SOP-02-132 Ph. Eur. 2.2.3 DIN 19268 DIN 38404-6 4-09-SOP-02-024-0

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Chemical testing	Medical devices / solutions	Test for determination	
		- Conductivity	Ph. Eur. 2.2.38 4-09-AS-00-215
		- Oxidizing substances	Ph. Eur. 2.5.30 4-09-SOP-02-170
		- Viscosity	Ph. Eur. 2.2.10 4-09-SOP-02-171
Microbiological-hygienic testing	Medical Devices	Sterility	DIN EN ISO 11737-2 Ph. Eur. 2.6.1 4-09-SOP-11-131
		Efficacy of antimicrobial preservation	Ph. Eur. 5.1.3 4-09-SOP-01-056
Physical testing	Medical devices, injection solutions and infusion preparations	Testing of particle contamination - microscopically method (visible and non-visible particles)	Ph. Eur. 2.9.19 Ph. Eur. 2.9.20 USP <788> DIN EN ISO 8536-4 DIN EN ISO 15747 4-09-SOP-11-129 4-09-SOP-11-181 4-09-SOP-11-182
		Test for effectiveness of the liquid filter	DIN EN ISO 8536-4 4-09-SOP-11-172
	Sterile barrier and packaging systems, materials	Tests within the framework of the proof of conformity	DIN EN ISO 11607-1
		- Accelerated aging	ASTM F1980 4-09-SOP-11-148
		- Strength of the sealing and gluing seams - Tightness of the sealing and gluing seams	DIN EN 868-5 (appendix C, appendix E) ASTM F1929 4-09-SOP-11-151 4-09-SOP-11-152

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Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Physical testing	Wound dressing materials	Test methods for primary dressings - Absorption behaviour (absorption)	DIN EN 13726-1 4-09-SOP-11-189
Environmental monitoring in production and testing of cleanliness of products according to DIN EN ISO 13485 : 2016-08[4], 6.4 and 7.5			
Chemical testing	Medical devices	Testing for residues - free iron - in metallic components	 ASTM A967/A967M 4-09-SOP-02-164 ASTM F2459 4-09-SOP-02-165
		Testing for protein residues	4-09-SOP-02-112 4-09-VA-14-003 (ISO/TS 15883-5)
Microbiological-hygienic testing	Medical devices	Determination of a population of microorganisms on products - (bioburden)	DIN EN ISO 11737-1 4-09-SOP-01-045 Applicable: DIN EN ISO 11138-1 DIN EN ISO 11138-7
		Microbiological examination of non-sterile products: microbial enumeration tests	Ph. Eur. 2.6.12 Ph. Eur. 5.1.4 4-09-SOP-01-056
		Microbiological examination of non-sterile products: test for specified micro-organisms	Ph. Eur. 2.6.13 Ph. Eur. 5.1.4 4-09-SOP-01-056
		Testing for endotoxins - Quantitative detection of endotoxins with Limulus Amoebocyte Lysate (LAL-Test)	Ph. Eur. 2.6.14 USP <85> USP <161> 4-09-SOP-11-130

Testing field	Test item Device(category)	Type of testing Test	Regulation Testing method
Environmental monitoring in production and testing of cleanliness of products according to DIN EN ISO 13485 : 2016-08[4], 6.4 and 7.5			
Microbiological-hygienic testing	Air	Determination of airborne biocontamination - by air sampler - by sedimentation plate	DIN EN ISO 14698-1 DIN EN ISO 14698-2 4-09-SOP-01-037 4-09-AS-01-007 Applicable: VDI 2083 Blatt 3 EU GMP Annex 1
	Surfaces	Determination of biocontamination by contact method	Ph. Eur. 2.6.8 4-09-SOP-11-126 Ph. Eur. 2.6.30 4-09-SOP-11-195
	Water	Total germ count – Purified water	Ph. Eur. 0008 Monograph 4-09-SOP-01-072
Physical testing	Clean room technology	Inspection of air conditioning systems - Differential pressure measurement between ranges of different air pressures - Airborne particle counting - Proof of the flow direction	DIN EN ISO 14644-1, -2, -3, -4 4-09-VA-14-002 4-09-AS-00-303 4-09-AS-14-002 Applicable: VDI 2083 Blatt 3

Regulations

DIN 19268 : 2007-05	pH-measurement – pH-measurement of aqueous solutions with pH measuring chains with pH glass electrodes and evaluation of measurement uncertainty
DIN 38404-6:1984-05 incl. Correction of 2018-12	German Standard methods for the examination of water, waste water and Sludge; physical and physico-chemical parameters (group C); determination of the oxidation-reduction potential, O.R.P. (C 6) including Corrigendum 1
DIN EN 868-5 : 2019-03	Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction – Requirements and test methods
DIN EN 13726-1 : 2002-06	Test methods for primary wound dressings — Part 1: Aspects of absorbency
DIN EN ISO 6872:2019-01	Dentistry –Ceramic materials
DIN EN ISO 8536-4 : 2013-07	Infusion equipment for medical use – Part 4: Infusion sets for single use, gravity feed
DIN EN ISO 10271 : 2011-10	Dentistry –Corrosion test methods for metallic materials
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 10993-2 : 2006-10	Biological evaluation of medical devices – Part 2: Animal welfare requirements
DIN EN ISO 10993-3 : 2015-02	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
DIN EN ISO 10993-4 : 2017-12	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
DIN EN ISO 10993-5 : 2009-10	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
DIN EN ISO 10993-6 : 2017-09	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
DIN EN ISO 10993-10 : 2014-10	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
DIN EN ISO 10993-11 : 2018-09	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
DIN EN ISO 10993-12 : 2012-10	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

DIN EN ISO 10993-13 : 2010-11	Biological evaluation of medical devices – Part 13: Identification and quantification of degradation products from polymeric medical devices
DIN EN ISO 10993-17 : 2009-08	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
DIN EN ISO 10993-18 : 2009-08	Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process
DIN EN ISO 11138-1:2017-07	Sterilization of health care products - Biological indicators - Part 1: General requirements
DIN EN ISO 11138-7:2019-11	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results
DIN EN ISO 11607-1 : 2017-10	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
DIN EN ISO 11737-1:2018-11	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
DIN EN ISO 11737-2:2010-04	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
DIN EN ISO 13402 : 2001-02	Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure
DIN EN ISO 14644-1 : 2016-06	Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness by particle concentration
DIN EN ISO 14644-2 : 2016-05	Cleanrooms and associated controlled environments – Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration
DIN EN ISO 14644-3 : 2006-03	Cleanrooms and associated controlled environments – Part 3: Test methods
DIN EN ISO 14644-4:2003-06	Cleanrooms and associated controlled environments-Part 4: Design, construction and start up
DIN EN ISO 14698-1:2004-04	Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods
DIN EN ISO 14698-2:2004-02	Cleanrooms and associated controlled environments - Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
DIN EN ISO 15747 : 2019-07	Plastic containers for intravenous injections

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DIN EN ISO 22674 : 2016-09	Dentistry – Metallic materials for fixed and removable restorations and appliances
ISO/TS 15883-5: 2005-11	Washer-disinfectors – Part 5: Test soils and methods for demonstrating cleaning efficacy
ASTM A967/A967M-17	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis
ASTM F756-17	Standard Practice for Assessment of Hemolytic Properties of Materials
ASTM F1089-18	Standard Test Method for Corrosion of Surgical Instruments
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM F2212-19	Standard Guide for Characterization of Type I Collagen as Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products (TEMPs)
ASTM F2459-18	Standard Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Ana lysis
EU GMP Annex 1	EU GMP Annex 1: Manufacture of Sterile Medicinal Products, 2008
OECD Guideline 402 : 2017-10	OECD Guideline for the Testing of Chemicals: Acute Dermal Toxicity
OECD Guideline 403 : 2009-09	OECD Guideline for the Testing of Chemicals: Acute Inhalation Toxicity
OECD Guideline 404 : 2015-07	OECD Guideline for the Testing of Chemicals: Acute dermal Irritation/Corrosion
OECD Guideline 405 : 2017-10	OECD Guideline for the Testing of Chemicals: Acute Eye Irritation/Corrosion
OECD Guideline 406 : 1992-07	OECD Guideline for the Testing of Chemicals: Skin Sensitisation
OECD Guideline 407 : 2008-10	OECD Guideline for the Testing of Chemicals: Repeated Dose 28-Day Oral Toxicity Study in Rodents
OECD Guideline 408 : 2018-06	OECD Guideline for the Testing of Chemicals: Repeated Dose 90-Day Oral Toxicity Study in Rodents
OECD Guideline 410 : 1981-05	OECD Guideline for the Testing of Chemicals: Repeated Dose Dermal Toxicity: 21/28-Day
OECD Guideline 411 : 1981-05	OECD Guideline for the Testing of Chemicals: Subchronic Dermal Toxicity: 90-Day

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OECD-Guideline 412 : 2018-06	OECD Guideline for the Testing of Chemicals: Subacute Inhalation Toxicity: 2-Day Study
OECD Guideline 413 : 2018-06	OECD Guideline for the Testing of Chemicals: Subchronic Inhalation Toxicity: 90-Day Study
OECD Guideline for testing of chemicals No. 414 : 2018-06	OECD Guideline for the Testing of Chemicals: Prenatal Developmental
OECD Guideline 416 : 1983-05	OECD Guideline for the Testing of Chemicals: Two-Generation Reproduction Toxicity
OECD Guideline 420 : 2001-12	OECD Guideline for the Testing of Chemicals: Acute Oral Toxicity – Fixed Dose Procedure
OECD Guideline 421 : 2016-07	OECD Guideline for the Testing of Chemicals: Reproduction/Developmental Toxicity Screening Test
OECD Guideline 422 : 2016-07	OECD Guideline for the Testing of Chemicals: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test
OECD Guideline 423 : 2002-02	OECD Guideline for the Testing of Chemicals: Acute Oral Toxicity – Acute Toxic Class Method
OECD Guideline 425 : 2008-10	OECD Guideline for the Testing of Chemicals: Acute Oral Toxicity – Up-and-Down Procedure
OECD Guideline 433 : 2018-06	OECD Guideline for the Testing of Chemicals: Acute Inhalation Toxicity: Fixed Concentration Procedure
OECD Guideline 439 : 2019-06	In Vitro Skin Irritation: Reconstructed Human Epidermis Test Method
OECD Guideline 443 : 2018-06	OECD Guideline for the Testing of Chemicals: Extended One-Generation Reproductive Toxicity Study
OECD Guideline 451 : 2018-06	OECD Guideline for the Testing of Chemicals: Carcinogenicity Studies
OECD Guideline 452 : 2018-06	OECD Guideline for the Testing of Chemicals: Chronic Toxicity Studies
OECD Guideline 453 : 2018-06	OECD Guideline for the Testing of Chemicals: Combined Chronic Toxicity/Carcinogenicity Studies
OECD Guideline 471 : 1997-07	OECD Guideline for the Testing of Chemicals: Genetic Toxicology: Salmonella typhimurium, Reverse Mutation Assay
OECD Guideline 483 : 2016-07	OECD Guideline for the Testing of Chemicals: Mammalian Spermatogonial Chromosome Abberation Test
OECD Guideline 487 : 2016-07	OECD Guideline for the Testing of Chemicals: In Vitro Mammalian Cell Micronucleus Test (MNvit)

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OECD Guideline 490 : 2016-07	OECD Guideline for the Testing of Chemicals: In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene
OECD Guideline 492: 2019-06	OECD Guideline for the Testing of Chemicals: Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling for eye irritation or serious eye damage
Ph. Eur. 10, 2.2.1	Clarity and degree of opalescence of liquids
Ph. Eur. 10, 2.2.2	Degree of coloration of liquids
Ph. Eur. 10, 2.2.3	Potentiometric determination of pH
Ph. Eur. 10, 2.2.5	Relative density
Ph. Eur. 10, 2.2.10	Viscosity - Rotating viscometer method
Ph. Eur. 10, 2.2.25	Absorption spectrophotometry, ultraviolet and visible
Ph. Eur. 10, 2.2.35	Osmolality
Ph. Eur. 10, 2.2.38	Conductivity
Ph. Eur. 10, 2.4.8	Heavy metal
Ph. Eur. 10, 2.5.30	Oxidising substances
Ph. Eur. 10, 2.6.1	Sterility
Ph. Eur. 10, 2.6.8	Pyrogens
Ph. Eur. 10, 2.6.9	Abnormal toxicity
Ph. Eur. 10, 2.6.12	Microbiological examination of non-sterile products: microbial enumeration tests
Ph. Eur. 10, 2.6.13	Microbiological examination of non-sterile products: test for specified micro-organisms
Ph. Eur. 10, 2.6.14	Bacterial endotoxins, Test for Pyrogens on rabbits
Ph. Eur. 10, 2.6.30	Monocyte-activation test
Ph. Eur. 10, 2.9.19	Particulate contamination: sub-visible particles
Ph. Eur. 10, 2.9.20	Particulate contamination: visible particles
Ph. Eur. 10, 3.1	Materials used for the manufacture of containers
Ph. Eur. 10, 3.2	Containers
Ph. Eur. 10, 3.3	Containers for human blood and blood components, and materials used in their manufacture; transfusion sets and materials used in their manufacture; syringes
Ph. Eur. 10, 5.1.3	Efficacy of antimicrobial preservation
Ph. Eur. 10, 5.1.4	Microbiological quality of non-sterile pharmaceutical preparations and substances for pharmaceutical use

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Ph. Eur. 10, Monographie 0008	Water, purified
Ph. Eur. 10, Monographie 1317	Ethanol (96 per cent)
Ph. Eur. 10, Monographie 1472	Sodium hyaluronate
USP 42 <85>	Bacterial Endotoxins
USP 42 <87>	Biological reactivity tests in vitro
USP 42 <88>	Biological reactivity tests in vivo
USP 42 <161>	Medical Devices – Bacterial Endotoxin an Pyrogen Tests
USP 42 <788>	Particulate Matter in Injections
USP 42 <1184>	Sensitization Testing
VDI 2083 Blatt 3 : 2005-07	Cleanroom technology Metrology and test methods
4-09-AS-00-215, Version 06	Bedienung und Wartung der Wasseraufbereitungsanlagen, Eigenkontrolle Wasserqualität
4-09-AS-00-303, Version 01	Differenzdruckmessungen zwischen Bereichen unterschiedlicher Luftdrücke / Umgang mit Differenzdruckmessgeräte
4-09-AS-01-001, Version 03	Probennahme bei Kunden: Abklatschproben
4-09-AS-01-007, Version 03	Mikrobiologische Untersuchung von Abklatsch - und Luftkeimproben nach Probennahme durch den Kunden
4-09-SOP-01-003, Version 03	Bestimmung der Keimzahl
4-09-SOP-01-036, Version 03	Bestimmung des Oberflächenkeimgehaltes auf Einrichtungs- und Bedarfsgegenständen (Abklatschverfahren)
4-09-SOP-01-037, Version 06	Luftkeimmessung
4-09-SOP-01-038, Version 04	Bestimmung des Oberflächenkeimgehaltes auf Einrichtungs- und Bedarfsgegenständen (Tupferverfahren)
4-09-SOP-01-045, Version 11	Bestimmung der Population von Mikroorganismen auf einem Produkt (Bioburden) nach DIN EN ISO 11737-1
4-09-SOP-01-046, Version 03	Prüfung auf ausreichende antimikrobielle Konservierung
4-09-SOP-01-056, Version 04	Mikrobiologische Prüfung nicht steriler Produkte
4-09-SOP-01-072, Version 01	Gesamtkeimzahl – Gereinigtes Wasser
4-09-SOP-02-024-0, Version 04	Potentiometrische pH-Wert-Bestimmung/Bestimmung der Redoxspannung in Lösungen
4-09-SOP-02-112, Version 03	Proteinbestimmung Biuret-Methode
4-09-SOP-02-115, Version 04	Bestimmung der Absorption einer Prüflösung von Materialien (Polyolefinen, Polyethylen, Polypropylen) zur Herstellung von Behältnissen

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4-09-SOP-02-116, Version 03	Prüfung auf sauer oder alkalisch reagierende Substanzen in Extrakten von Material zur Herstellung von Behältnissen; Behältnisse
4-09-SOP-02-117, Version 03	Prüfung auf reduzierende Substanzen in Material zur Herstellung von Behältnissen; Behältnisse
4-09-SOP-02-118, Version 03	Prüfung auf hexanlösliche Substanzen in Material zur Herstellung von Behältnissen; Behältnisse
4-09-SOP-02-119, Version 03	Titandioxid in Materialien für Behältnisse, Behältnissse
4-09-SOP-02-121, Version 04	Prüfung von Klarheit und Opaleszenz von Flüssigkeiten
4-09-SOP-02-122, Version 03	Bestimmung der Färbung von Flüssigkeiten und Probelösungen nach EP
4-09-SOP-02-123, Version 02	Prüfung auf dioxanlösliche Substanzen aus Kunststoffen
4-09-SOP-02-127, Version 03	Prüfung der Identität und Reinheit von Ethanol (96%)
4-09-SOP-02-128, Version 05	Chirurgische und zahnärztliche Handinstrumente: Bestimmung der Beständigkeit gegenüber Sterilisation, Korrosion und Wärmebehandlung
4-09-SOP-02-131, Version 04	Untersuchungen zur Reinheit von Natriumhyaluronat
4-09.SOP-02-132, Version 06	Bestimmung der Osmolalität
4-09-SOP-02-133, Version 03	Bestimmung der chemischen Löslichkeit von dentalen Metallkeramiksystemen
4-09-SOP-02-134, Version 05	Chemische Charakterisierung von Werkstoffen und Medizinprodukten
4-09-SOP-02-138, Version 02	Bestimmung der Dichte in Flüssigkeiten
4-09-SOP-02-140, Version 04	Quantitativer Nachweis von Schwermetallen
4-09-SOP-02-148, Version 02	Korrosionsverfahren für metallische Werkstoffe, Zahnheilkunde: statische Eintauchprüfung und statische Eintauchprüfung mit periodischer Analyse
4-09-SOP-02-149, Version 03	Anlaufprüfung - Metallische Werkstoffe für festsitzenden und herausnehmbaren Zahnersatz und Vorrichtungen
4-09-SOP-02-160, Version 01	Überprüfung der Reinigung eines Blisterautomats durch Nachweis von Acetylsalicylsäure mittels HPLC
4-09-SOP-02-161, Version 01	Konzentrationsbestimmung von Salicylsäure
4-09-SOP-02-164, Version 02	Nachweis von freiem Eisen auf passivierten Prüfkörpern aus rostfreiem Stahl
4-09-SOP-02-168, Version 01	Bestimmung der Reinheit von Materialien zur Herstellung von Behältnissen; Behältnissen - Elementbestimmung mittels ICP

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4-09-SOP-02-170, Version 01	Oxidierende Substanzen
4-09-SOP-02-171, Version 01	Viskositätsbestimmungen
4-09-SOP-02-172, Version 01	Bestimmung des Polyhexanid-Gehalts
4-09-SOP-03-022, Version 13	Biologische Prüfung von Medizinprodukten. Zytotoxizitätstest an in vitro kultivierten L 929-Zellkulturen gemäß ISO 10993-5 (EN 30993-5)
4-09-SOP-03-023, Version 04	Zytotoxizitätstest an in vitro kultivierten VERO-Zellkulturen gemäßAustralian Standard AS 2696-1989, Appendix C
4-09-SOP-03-024, Version 05	Biologische Prüfung von Medizinprodukten. Zytotoxizitätstest an in vitro kultivierten L929 Zellen gemäß USP
4-09-SOP-03-025, Version 03	Prüfung auf in vitro-Zytotoxizität (Prüfung durch direkten Kontakt) DIN EN ISO 10993-5
4-09-SOP-03-026, Version 04	Prüfung auf in vitro-Zytotoxizität (Prüfung durch indirekten Kontakt) DIN EN ISO 10993-5
4-09-SOP-03-030, Version 03	Prüfung von Medizinprodukten, Zytotoxizitätstest an in vitro kultivierten L929-Zellen gemäß ISO 10993-5 (Prüfung von Extrakten) - MTS-basierter Viabilitätsassay
4-09-SOP-03-031, Version 02	Prüfung von Medizinprodukten, Zytotoxizitätstest an in vitro kultivierten L929-Zellen gemäß ISO 10993-5 (Test von Flüssigkeiten) – MTS-basierter Viabilitätsassay
4-09-SOP-11-122, Version 06	Prüfung auf intrakutane Reaktivität
4-09-SOP-11-123, Version 07	Prüfung auf Sensibilisierung
4-09-SOP-11-124, Version 07	Prüfung auf akute systemische Toxizität (parenterale Applikation) nach DIN EN ISO 10993-11
4-09-SOP-11-126, Version 06	Pyrogentest (Kaninchen)
4-09-SOP-11-128, Version 08	Prüfung auf Irritation (an der Haut)
4-09-SOP-11-130, Version 08	Prüfung auf Endotoxinfreiheit (LAL)
4-09-SOP-11-131, Version 07	Prüfung auf Sterilität
4-09-SOP-11-132, Version 06	Prüfung auf Genotoxizität Bakterieller Rückmutationstest (Agarplattenmethode)
4-09-SOP-11-133, Version 06	Prüfung auf Irritation am Auge, ISO 10993-10
4-09-SOP-11-134, Version 06	Prüfung auf Hämokompatibilität
4-09-SOP-11-135, Version 03	Prüfung auf subakute Toxizität
4-09-SOP-11-136, Version 06	Prüfung auf subchronische Toxizität (MP-Prüfung)
4-09-SOP-11-137, Version 03	Prüfung auf Irritation an der Mundschleimhaut, ISO 10993-10

-Translation-

4-09-SOP-11-139, Version 08	Prüfung auf lokale Effekte nach Implantation
4-09-SOP-11-147, Version 04	Prüfung auf Sensibilisierung nach Magnusson und Kligman
4-09-SOP-11-148, Version 03	Künstliche Alterung von Sterilverpackungen für Medizinprodukte
4-09-SOP-11-151, Version 03	Siegelnahtbreite von Sterilverpackungen von Medizinprodukten
4-09-SOP-11-152, Version 06	Undurchlässigkeit und Kontinuität der Siegelung durch Fusion oder Adhäsion - Prüfverfahren
4-09-SOP-11-153, Version 05	Prüfung auf Genotoxizität (Mouse Lymphoma Assay)
4-09-SOP-11-156, Version 03	Prüfung auf systemische und lokale Effekte nach subkutaner Implantation nach ISO 10993-6
4-09-SOP-11-157, Version 06	Prüfung auf histopathologische Veränderungen
4-09-SOP-11-160, Version 04	Durchführung des Lokalen Lymphknoten Assays (LLNA) zur Prüfung des Hautreizungspotentials von Substanzen
4-09-SOP-11-162, Version 01	Prüfung auf subchronische Toxizität nach Applikation durch Inhalation
4-09-SOP-11-164, Version 04	Durchführung des In-vitro-Mikronukleus-Assay (MNA) zur Prüfung der Genotoxität von Substanzen
4-09-SOP-11-165, Version 03	Prüfung auf akute orale Toxizität - Akute toxische Klassenmethode
4-09-SOP-11-166, Version 01	Prüfung auf akute dermale Toxizität
4-09-SOP-11-167, Version 02	Prüfung auf rektale Irritation
4-09-SOP-11-170, Version 02	Prüfung auf penile Irritation nach ISO 10993-10
4-09-SOP-11-171, Version 05	Prüfung auf Genotoxizität (Fluctuation test)
4-09-SOP-11-172, Version 03	Prüfung von Infusionsgeräten für Schwerkraftinfusionen
4-09-SOP-11-180, Version 02	Vaginale Irritationsprüfung
4-09-SOP-11-181, Version 01	Prüfung auf Partikelkontamination - sichtbare Partikel
4-09-SOP-11-182, Version 02	Partikelbestimmung in Kunststoffbehältnissen für intravenöse Injektionen
4-09-SOP-11-184, Version 01	Charakterisierung von Collagen I in medizinischen Produkten
4-09-SOP-11-185, Version 03	Prüfung auf Hämolyse nach ASTM
4-09-SOP-11-186, Version 01	Prüfung auf intrakutane Reaktivität USP <88>
4-09-SOP-11-187, Version 01	Prüfung auf akute systemische Toxizität USP <88>
4-09-SOP-11-188, Version 01	Implantationstest USP <88>
4-09-SOP-11-189, Version 01	Prüfverfahren für primäre Verbandstoffe

-Translation-

4-09-SOP-11-191, Version 02	Prüfung auf Komplementaktivierung
4-09-SOP-11-195, Version 02	Prüfung auf Monozytenaktivierung
4-09-SOP-20-129, Version 02	In-vitro-Prüfung auf Haut-Irritation durch Chemikalien (EpiSkinTM)
4-09-SOP-20-196, Version 02	In-vitro-Prüfung auf Augen-Irritation durch flüssige Chemikalien (SkinEthic TM)
4-09-SOP-20-197, Version 01	In-vitro-Prüfung auf Augen-Irritation durch feste Chemikalien (SkinEthic TM)
4-09-VA-14-002, Version 04	Durchführung der Überprüfung von Betriebsparametern in Reinräumen und Reinigungsvalidierung
4-09-VA-14-003, Version 02	Überprüfung der Reinigungsleistung - Proteinrückstände auf Medizinprodukten

Abbreviations

AS	Arbeitsvorschrift
ASTM	American Society for Testing and Materials
DIN	Deutsches Institut für Normung
EN	Europäische Norm
IEC	International Electrotechnical Commission
ISO	International Organization for Standardization
OECD	Organisation for Economic Co-operation and Development
Ph. Eur.	European Pharmacopoeia
SOP	Standard Operating Procedure
USP	United States Pharmacopeia
VA	Verfahrensanweisung
VDI	Verein Deutscher Ingenieure e.V.

[1] DIN EN ISO/IEC 17025 : 2018-08 General requirements for the competence of testing and calibration laboratories

[2] Council Directive 93 / 42 / EEC of 14 June 1993 concerning medical devices

[3] Council Directive 90 / 385 /EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

[4] DIN EN ISO 13485 : 2016-08 Medical devices — Quality management systems —. Requirements for regulatory purposes