Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER

State Secretariat for Economic Affairs SECO
Swiss Accreditation Service SAS

STS Directory

Accreditation number: STS 0504

International standard:	ISO/IEC 17025:2017
Swiss standard:	SN EN ISO/IEC 17025:2018

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Initial accreditation:	08.08.2008
Current accreditation:	08.08.2023 to 07.08.2028
Scope of accreditation see:	www.sas.admin.ch (Accredited bodies)

Scope of accreditation as of 14.02.2025

Testing laboratory, Type B, for microbiological, chemical, biological and physical analysis of medical devices, pharmaceuticals and environments

Group of products or materials, field of activity	Principle of measurement [2] (characteristics, measuring ranges, type of test)	Test methods, remarks (national, international standards, in-house test methods)
	Methods **Biological / biochemical**	
	Microbiological methods	
Product (liquid, powder, medical devices) for single or multiple use in different materials	Sterility test	Internal procedure WI 33, EN ISO 11737-2, Ph. Eur. 2.6.1
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	Microbial load test (Bioburden)	Internal procedure WI 35 Ph. Eur. 2.6.12 EN, ISO 11737-1
Biological indicators	Population control of biological indicators	Internal procedure WI 27, EN ISO 11138-1 and 11138-2

1) Scope of accreditation type A (fix)
2) Scope of accreditation type B (flexible)
3) Scope of accreditation type C (flexible)

Definition of flexibilty see SAS Document 741

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Group of products or materials, field of activity	Principle of measurement [2] (characteristics, measuring ranges, type of test)	Test methods, remarks (national, international standards, in-house test methods)
Biological indicators	Incubation for sterility test	Internal procedure SOP 7.5.1-4, WI 25-b ISO 11138 EN ISO 14161 ISO 11135-1
Microbial characterization of pure cultures of bacteria from air, surfaces, liquids and solids	Identification/biochemical characterization of germs	Internal procedures WI 113 and WI 38, Ph. Eur. 5.1.6, USP 1113, ISO 11737-1
	Microscopy	
Microbial characterization of pure cultures of bacteria from air, surfaces, liquids and solids	Gram staining and simple identification of bacteria	Internal procedure WI 38 ISO 11737-1
	Cell culture methods	
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	In Vitro cytotoxicity	Internal procedure WI 47, WI 56 ISO 10993-5 and ISO 10993-12
Product (liquid, powder, gel)	In Vitro skin irritation - Detection by colorimetry MTT	Internal procedures WI 169, OECD TG 439
Extract (single- and multiple-use medical devices in various materials)	In Vitro skin irritation - Detection by colorimetry MTT	Internal procedures WI 179, ISO 10993-23 and ISO 10993-12
	Chemical methods	
	Spectrometry	
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	Protein assay	Internal procedure WI 96, WI96-b, Ph. Eur. 2.5.33 (method n°4), USP 1057 (method n°4), ISO 15883-1 (modified)
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	Bacterial endotoxin test (kinetic colorimetric method)	Internal procedure WI 31, ISO 11737-3, Ph. Eur. 2.6.14 (method D) and USP 85 (chromogenic technique), JP, AAMI st 72

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Group of products or materials, field of activity	Principle of measurement [2] (characteristics, measuring ranges, type of test)	Test methods, remarks (national, international standards, in-house test methods)
	Gas chromatography (GC):	
	GC-FID	
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	Analysis of Ethylene Oxide (EO) and Chloroethanol (ECH) in water	Internal procedure WI 77c ISO 10993-7 and ISO 10993-12
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	Analysis of Ethylene Oxide (EO) and Chloroethanol (ECH)	Internal procedure WI 77 ISO 10993-7 and ISO 10993-12
Product or extract (liquid, powder, single-use or multiple-use medical devices in different materials)	Analysis of Ethylene Glycol (EG) residues	Internal procedure WI 60b ISO 10993-7 and ISO 10993-12
	GC-MS	
Medical devices (or others) with plastic (PVC) components Medical devices (solid), polar, semi-polar and non-polar extracts	Extraction and Quantitative Analysis of 13 Phthalates	Internal procedure WI 143 ISO 10993-18 EPA 8270 modified EPA 525 modified
Solid samples, liquid samples, medical devices and/or materials for food contact	Extraction and quantitative analysis of 15 bisphenols with derivatization	Internal procedure WI 165 ISO 10993-18 EU 10/2011 SR 817.023.21
Analysis of solid medical devices, organic solvent extract and liquid samples	Extraction and analysis of C10-C40 hydrocarbons	Internal procedure WI 174 ISO 9377-2 modified ISO 19227, NF S94-091
Medical devices (solid), polar, semi-polar and non-polar extracts	Quantitative and semi-quantitative analysis (screening) VOC by HS-Trap-GC-MS	Internal procedure WI 157 ISO 10993-18 EPA 8260 modified
Medical devices (solid), polar, semi-polar and non-polar extracts	Quantitative and semi-quantitative analysis (screening) SVOC by HS-GC-MS	Internal procedure WI 158 ISO 10993-18 EPA 8270 modified
	FTIR	
Syringe-type (or other) medical devices, semi-polar intermediate extract	Gravimetric analysis and qualitative identification of Poly(dimethylsiloxane) (PDMS) residues by FTIR	Internal procedure WI 156 ISO 10993-18 ISO 7886-1 modified
	General chemistry	
Water and aqueous extracts (powder, single-use or multiple-use medical devices in various materials)	TOC Determination of total organic carbon in water or an aqueous extract	Internal procedure WI 130 EN 1484 (water), Ph. Eur. 2.2-44 (water), USP 643 (water), ISO 10993-12 (extraction)

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Group of products or materials, field of activity	Principle of measurement [2] (characteristics, measuring ranges, type of test)	Test methods, remarks (national, international standards, in-house test methods)
	Gravimetry	
Solid samples and/or materials for food contact	Global migration, simulating E (TENAX)	Internal procedure WI 175 NF EN 1186-1, 1186-11 1186-13, 14338 SR 817.023.21, EU 10-2011
	Physical methods	
Water and/or aqueous extracts (single- or multiple-use medical devices in various materials)	Particle counting in liquids by light extinction	Internal procedure WI 52-b ISO 21501-3, USP 788, USP 789 Ph. Eur. 2.9.19
Various packaging	Burst Test: Standard Test Method for Internal Pressurization Failure Resistance of Unrestrained Packages	Internal procedure WI 43-c ASTM F1140-F1140M (method A)
	Seal Peel: Standard Test Method for Seal Strength of Flexible Barrier Materials	Internal procedure WI 43-f ASTM F88-F88M (technique A)
	Bubble Test: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization	Internal procedure WI 43-b ASTM F2096
	Dye Migration: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Internal procedure WI 43-d ASTM F1929
	Dye Migration: Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	Internal procedure WI 43-d ASTM F3039 (method A)
	Visual Inspection: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Internal procedure WI 112 ASTM F1886-F1886M
	Accelerated Aging Test: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Internal procedure WI 43-a ASTM F1980
Various types of containers, packaging or packaging components	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Internal procedure WI 43-g ASTM D4332

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