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 0529

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

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Initial accreditation:	05.02.2010
Current accreditation:	05.02.2020 to 04.02.2025
Scope of accreditation see:	www.sas.admin.ch (Accredited bodies)

Scope of accreditation as of 06.07.2023

Testing laboratory for materials, implants and types of packaging for osteosynthesis products

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)
Materials Analysis		
	Testing of metallic materials - Rotating bar bending fatigue test	DIN 50113
	Viscometry - Measurement of kinematic viscosity by means of the Ubbelohde viscometer - Part 1: Viscometer specification and measurement procedure	DIN 51562-1
	Plastics – Determination of tensile properties – Part 1: General principles	ISO 527-1
	Plastics – Determination of tensile properties – Part 2: Test conditions for moulding and extrusion plastics	ISO 527-2

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)
Structural examination of metals	Metallic materials – Rotating bar bending fatigue testing	ISO 1143
	Plastics – Determination of the viscosity of polymers in dilute solution using capillary viscometer	ISO 1628-1
	Metallic materials – Vickers hardness test	ISO 6507
	Plastics – Determination of water content	ISO 15512
	Standard Test Methods for Determining the Inclusion Content of Steel	ASTM E45 Method A
	Standard Test Methods for Determining Average Grain Size	ASTM E112
	Microstructural standards for alpha+beta titanium alloy bars	ETTC-2
	Steels –Micrographic determination of the apparent grainsize	ISO 643
	Implants for surgery – Metallic materials – Classification of microstructures for alpha+beta titanium alloy bars	ISO 20160
Testing of osteosynthesis devices	Standard Specification and Test Method for Metallic Bone Plates	ASTM F382
	Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices	ASTM F384
	Standard Specification and Test Methods for Metallic Medical Bone Screws	ASTM F543
	Standard Specification and Test Methods for Intramedullary Fixation Devices	ASTM F1264
	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	ASTM F1717

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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)
	Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	ASTM F1798
	Test Methods for Intervertebral Body Fusion Devices	ASTM F2077
	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression	ASTM F2267
	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants	ASTM F2502 (Annexes 1 and 4)
	Implants for surgery – Metal bone screws with asymmetrical thread and spherical under-surface – Mechanical requirements and test methods	ISO 6475
	Implants for surgery – Determination of bending strength and stiffness of bone plates	ISO 9585
	Static cantilever bending testing of metallic bone screws	In-house method 103420478
	Clinical Reprocessing simulation (washing/disinfection and autoclaving)	In-house method SE_093680
	Visual inspection of external instrument surfaces	In-house method SE_694258
	Visual inspection of internal instrument surfaces by endoscope	In-house method SE_840210
Testing of packaging for osteosynthesis devices		
	Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88/F88M
	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	ASTM F1886/F1886M

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

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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)**
	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	ASTM F1929 (Method A)
	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	ASTM F3039 (Method A)

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