

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

Synthes GmbH

Material Science and Testing

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Initial accreditation: 05.02.2010

Current accreditation: 05.02.2025 to 04.02.2030

Scope of accreditation see: <u>www.sas.admin.ch</u>

(Accredited bodies)

Scope of accreditation as of 08.04.2025

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
	Metallic materials – Rotating bar bending fatigue testing	ISO 1143
Testing of osteosynthesis devices		
	Standard Specification and Test Method for Metallic Bone Plates	ASTM F382
	Standard Specifications and Test Methods for Metallic Angled Ortho- pedic Fracture Fixation Devices	ASTM F384

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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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	Standard Specification and Test Methods for Metallic Medical Bone Screws	ASTM F543
	Standard Specification and Test Methods for Intramedullary Fixa- tion Devices	ASTM F1264
	Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	ASTM F1717
	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

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¹⁾ Scope of accreditation type A (fix)

²⁾ Scope of accreditation type B (flexible)

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	Visual inspection of external instrument surfaces	In-house method SE_694258
	Visual inspection of internal instrument surfaces by endoscope	In-house method SE_840210

In case of contradictions in the language versions of the directories, the German version shall apply.

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