



## SCESm Directory

Accreditation number: SCESm 0013

International standard: ISO/IEC 17021-1:2015  
Swiss standard: SN EN ISO/IEC 17021-1:2015

Swiss Safety Center AG  
Certifications  
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Internet: [www.safetycenter.ch](http://www.safetycenter.ch)  
Initial accreditation: 16.03.1994  
Current accreditation: 01.07.2024 to 30.06.2029  
Scope of accreditation see: [www.sas.admin.ch](http://www.sas.admin.ch)  
(Accredited bodies)

### Scope of accreditation as of 08.06.2026

#### Certification body for management systems in the areas of quality, environment and security

Standards	Approved technical scopes	Remarks
ISO 9001:2015		IAF Code
	Agriculture, fishing	1
	Mining and quarrying	2
	Food products, beverages and tobacco	3
	Textiles and textile products	4
	Leather and leather products	5
	Wood and wood products	6
	Pulp, paper and paper products	7
	Publishing companies	8
	Printing companies	9
	Manufacture of coke and refined petroleum products	10
	Nuclear fuel	11
Chemicals, chemical products and fibres	12	



## SCESm Directory

## Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
	Pharmaceuticals	13
	Rubber and plastic products	14
	Non-metallic mineral products	15
	Concrete, cement, lime, plaster etc.	16
	Basic metals and fabricated metal products	17
	Machinery and equipment	18
	Electrical and optical equipment	19
	Shipbuilding	20
	Aerospace	21
	Other transport equipment	22
	Manufacturing not elsewhere classified	23
	Recycling	24
	Electricity supply	25
	Gas supply	26
	Water supply	27
	Construction	28
	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods	29
	Hotels and restaurants	30
	Transport, storage and communication	31
	Financial intermediation, real estate, renting	32
	Information technology	33
	Engineering services	34
	Other services	35
	Public administration	36
	Education	37
	Health and social work	38
	Other social services	39
ISO 14001:2015		IAF Code
	Agriculture, fishing	1
	Food products, beverages and tobacco	3
	Textiles and textile products	4



**SCESm Directory**

**Accreditation number: SCESm 0013**

Standards	Approved technical scopes	Remarks	
ISO 45001:2018	Wood and wood products	6	
	Pulp, paper and paper products	7	
	Publishing companies	8	
	Printing companies	9	
	Chemicals, chemical products and fibres	12	
	Pharmaceuticals	13	
	Rubber and plastic products	14	
	Concrete, cement, lime, plaster etc.	16	
	Basic metals and fabricated metal products	17	
	Machinery and equipment	18	
	Electrical and optical equipment	19	
	Other transport equipment	22	
	Manufacturing not elsewhere classified	23	
	Recycling	24	
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	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods	29	
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	Engineering services	34	
	Other services	35	
	Occupational safety and health management systems		IAF Code
	Agriculture, fishing		1
	Mining and quarrying		2
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## SCESm Directory

## Accreditation number: SCESm 0013

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	Education	37
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	Other social services	39
	Energy Management Systems - Industry – light to medium - Industry – heavy - Mining - Energy supply - Buildings - Building complexes - Transport - Agriculture	The certification body fulfils the requirements of the standard ISO 50003:2021
	Quality requirements for welding	Combined with a certification based on ISO 9001:2015 (Replaces EN 729-2)
ISO 3834-2:2021 ISO 3834-3:2021 ISO 3834-4:2021	comprehensive - standard - elementary - quality requirements	
ISO 21001:2018	Provider of learning services for non-formal education and training	
eduQua:2021	Continuing education	Corresponds to IAF-Code 37 Already granted certificates according to the standard
IN-Qualis:2018	Work integration	
SR 930.113: Regulation on the safety of simple Pressure Vessels (Pressure Vessel regulation) from 25.11.2015 (as constituted on 20.04.2016)	Module H	Conformity assessment body according to SR 930.113  Indication: Modules B, C1 and C2 are covered under the Swiss Safety Center AG accreditation SCESp 0063
EU directive for simple pressure vessels 2014/29/EU of 02/26/2014		Module C is covered under the Swiss Safety Center AG accreditation SIS 0073  Notified Body EU identification number NB 1253 according to 2014/68/EU article 17



## SCESm Directory

## Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
SR 930.114: Regulation on the safety of pressure equipment (Pressure Equipment Ordinance)  (EC Pressure Equipment Directive 2014/68/EU) of 05/15/2014	Module H	Conformity assessment body according to SR 930.114  Certification body for the conformity assessment procedure, 2014/68/EU, Annex III  Indication: The modules B-Type examination, B- production type, C2, F, G, D, D1, E, E1 und H1 are covered by SCESp 0063  The module A2 is covered by SIS 0073  Notified Body EU identification number NB 1253 according to 2014/68/EU article 20
SR 930.112: Ordinance on the safety of lifts  Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts ("Lift Safety Directive")	Elevator	Lift Safety Directive 2014/33/EU - Annex VII (Module H)  Explicitly excluded are design examinations according to Lift Safety Directive, Annex XI (3.3)
ISO/IEC 20000-1:2018	IT Service Management Systems	The certification body fulfils the requirements of the standard ISO/IEC 20000-6:2017
ISO/IEC 27001:2022	Information Security Management Systems ISMS	The certification body fulfils the requirements of the standard ISO/IEC 27006-1:2024
ISO 22000:2018	Food safety management systems for the clusters (according to ISO 22003-1:2022)  1. Category B; only BIII – Pre-process handling of plant products  2. Processing food for humans and animals (C + D)  4. Retail, transport and storage (F + G)  6. Packaging material (I)	Fulfils the requirements of ISO 22003-1:2022 for the sectors  B Farming or handling of plants  C Food, ingredient and pet food processing D Feed and animal food processing  F Trading, retail and e-commerce G Transport and Storage Services  I Production of Packaging Materials



**SCESm Directory**

**Accreditation number: SCESm 0013**

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ISO 13485:2016	<p>8. Bio/chemical (K)</p> <p><b>NON-ACTIVE MEDICAL DEVICES</b></p> <p><b>General non-active, non-implantable medical devices</b></p> <p>Non-active devices for anaesthesia emergency and intensive care</p> <p>Non-active devices for injection, infusion, transfusion and dialysis</p> <p>Non-active orthopaedic and rehabilitation devices</p> <p>Non-active medical devices with measuring function</p> <p>Non-active ophthalmologic devices</p> <p>Non-active instruments</p> <p>Non-active medical devices for disinfecting, cleaning, rinsing</p> <p><b>Devices for wound care</b></p> <p>Bandages and wound dressings</p> <p>Suture material and clamps</p> <p>Other medical devices for wound care</p> <p><b>Non-active dental devices and accessories</b></p> <p>Non-active dental devices/equipment and instruments</p> <p>Dental materials</p> <p>Dental implants</p> <p><b>Non-active medical devices other than specified in table 1.1</b></p> <p>To be specified in advance</p> <p><b>ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES</b></p> <p><b>General active medical devices</b></p> <p>Active surgical devices</p>	<p>K Chemical and bio-chemical</p> <p>Technical scope according to IAF MD 8:2023 - Table A 1.1 Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives</p> <p>Limitations see below</p> <p>Technical scope according to IAF MD 8:2023 - Table A 1.2 Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives</p>



## SCESm Directory

## Accreditation number: SCESm 0013

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	<p>Active dental devices</p> <p>Active devices for disinfection and sterilisation</p> <p>Active rehabilitation devices and active prostheses</p> <p>Active devices for patient positioning and transport</p> <p><b>Non-active medical devices other than specified in table 1.1</b></p> <p>To be specified in advance</p> <p><b>STERILIZATION METHODS FOR MEDICAL DEVICES</b></p> <p><b>Moist heat</b></p> <p>Disposable new and reusable devices or part of it</p> <p><b>Aseptic processing</b></p> <p>Disposable new and reusable devices or parts of it</p> <p><b>Hydrogen peroxide</b></p> <p>Disposable new and reusable devices or parts of it</p> <p><b>PARTS AND SERVICES</b></p> <p><b>Raw materials</b></p> <p>Raw metals, plastic, wood, ceramic</p> <p><b>Components</b></p> <p>Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic</p>	<p>Technical scope according to IAF MD 8:2023 - Table A 1.5 Mainly relevant for MS of specialized sterilizers / contractors and/or manufacturers of medical devices and / or their legal representatives</p> <p>Technical scope according to IAF MD 8: 2023 – Table A 1.7 Mainly relevant for MS of manufacturers and / or sub-assemblers and / or distributors of medical devices Together with appropriate knowledge of the relevant IAF Codes in the corresponding product category</p>



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Accreditation number: SCESm 0013

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	<p><b>Subassemblies</b></p> <p>Electronic and mechanical subassemblies, made to drawings and/or work instructions area</p> <p><b>Calibration services</b></p> <p>Verification/confirmation services for measuring instruments, tools and test fixtures</p> <p><b>Distribution services</b></p> <p>Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices</p> <p><b>Maintenance services</b></p> <p>Electrical or mechanical repair services</p> <p>Facility cleaning and maintenance services</p> <p>Uniform cleaning and testing of ESD smocks</p> <p><b>Transportation services</b></p> <p>Trucking, shipping</p> <p>Air transportation service in general</p> <p><b>Other services</b></p> <p>Consulting services related to medical devices</p> <p>Packaging services</p>	

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

### Limitations:

- probes and catheters for urology, gastroenterology, respiratory tract and surgical aspiration
- equipment for parenteral and enteral nutrition
- needles for infusion and excision
- canulas, probes, tubes
- plastic tubes for infusion and excision
- filters for blood and liquor, other filters



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Abbreviation	Signification
eduQua	Certification body for quality management system in adult training institutes, Ref. <a href="http://www.eduqua.ch">www.eduqua.ch</a>
IAF Code	International Accreditation Forum Code; see also IAF ID1, Informative Document for QMS and EMS Scopes of Accreditation
ITSM	IT Service Management
MDO	Swiss Medical Device Ordinance, SR 812.213, of the 17 October 2001

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