

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

Swiss Accreditation Service SAS

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
Richtistrasse 15
8304 Wallisellen

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Internet: <u>www.safetycenter.ch</u>

Initial accreditation: 16.03.1994

Current accreditation: 01.07.2019 to 30.06.2024

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

(Accredited bodies)

Scope of accreditation as of 07.03.2024

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 to- bacco	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

07.03.2024 / BN asa/sts 0013scesmvz en.docx 1/11

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
ISO 9001:2015	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

07.03.2024 / BN asa/sts 0013scesmvz en.docx 2/11

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
ISO 14001:2015	Food products, beverages and to- bacco	3
	Textiles and textile products	4
	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
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	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods	29
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	Transport, storage and communication	31
	Information technology	33
	Engineering services	34
	Other services	35

07.03.2024 / BN asa/sts 0013scesmvz en.docx 3/11

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

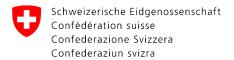
Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
ISO 45001:2018	Occupational safety and health management systems	
		IAF Code
	Agriculture, fishing	1
	Mining and quarrying	2
	Food products, beverages and to- bacco	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
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07.03.2024 / BN asa/sts 0013scesmvz en.docx 4/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

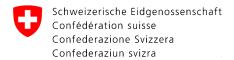
Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
ISO 45001:2018	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
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	Other social services	39
	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	
SN EN ISO 3834-2:2006 (ISO 3834-2:2005)	Quality requirements for welding, Comprehensive quality require- ments	Certificates according to the series of standards SN EN ISO 3834-X:2006 res. ISO 3834-X:2005 remain valid until 30.04.2024 at the latest
ISO 21001:2018	Provider of learning services for non-formal education and training	
eduQua:2021 eduQua:2012	Continuing education	Corresponds to IAF-Code 37 Already granted certificates ac- cording to the standard edu- Qua:2012 keep their validity until 30.06.2025, at the latest
IN-Qualis:2018	Work integration	

07.03.2024 / BN asa/sts 0013scesmvz en.docx 5/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

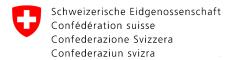
Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
SR 930.113: Regulation on the safety of simple Pressure Vessels (Pressure Vessel regulation) from 25.11.2015 (as constituted on 20.04.2016) EU directive for simple pressure	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.
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
SR 930.114 Regulation on the safety of pressure equipment (Pressure Equipment Ordinance)	Module H	2014/68/EU article 17 Conformity assessment body according to SR 930.114 Certification body for the conform-
(EC Pressure Equipment Directive 2014/68/EU) of 05/15/2014		ity 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
Ordinance on the safety of lifts, SR 930.112	Elevator	Lift Safety Directive 2014/33/EU - Annex XI (Module H1)
Directive 2014/33/EU on the har- monisation of the laws of the Mem- ber States relating to lifts and safety components for lifts ("Lift Safety Directive")		Explicitly excluded are design examinations according to Lift Safety Directive, Annex XI (3.3)
SCC	Safety Certificate Contractors	
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 27006:2015/Amd. 1:2020

07.03.2024 / BN asa/sts 0013scesmvz en.docx 6/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

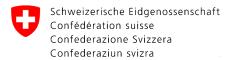
Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
ISO/IEC 27001:2013	Information Security Management Systems ISMS	Already granted certificates according to the standard ISO/IEC 27001:2013 keep their validity until 31.10.2025, at the latest
ISO 22000:2018	Food safety management systems for the clusters (according to ISO/TS 22003)	The certification body satisfies the requirements according to ISO/TS 22003:2013 for the sectors
	Cluster	
	2. Food and Feed Processing (C + D)	C Food Manufacturing D Animal Feed Production
	4. Retail, transport and storage (F + G)	F Distribution G Provision of Transport and Storage Services
	5. Auxiliary Services (I)	Production of Food Packaging and Packaging Materials
	6. (Bio) Chemicals (K)	K Production of (Bio) Chemicals
ISO 22000:2018 ISO/TS 22002-1:2009 Inclusive additional FSSC 22000 requirements version 5	Food Safety System Certification 22000 (FSSC 22000) for the categories:	Edition 5.1 Including ISO/TS 22003:2013
	CI Processing of perishable animal products CII Processing of perishable plant products CIII Processing of perishable animal and plant products (mixed products) CIV Processing of ambient stable products (ambient temperature) DII Production of Pet Food for dog and cat	
ISO 22000:2018 ISO/TS 22002-6:2016 Inclusive additional FSSC 22000 requirements version 5	DI Production of Feed DII Production of Pet Food for other pet than dog and cat	Edition 5.1 Inclusive ISO/TS 22003:2013
ISO 22000:2018 ISO/TS 22002-5:2019 Inclusive additional FSSC 22000 requirements version 5	GI Provision of Transport and Storage Services for Perishable Food and Feed GII Provision of Transport and Storage Services for Ambient Stable Food and Feed.	Edition 5.1 Inclusive ISO/TS 22003:2013

07.03.2024 / BN asa/sts 0013scesmvz en.docx 7/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

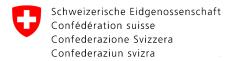
Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
ISO 22000:2018 ISO/TS 22002-4:2013 Inclusive additional FSSC 22000 requirements version 5	I Production of Food Packaging and Packaging Material	Edition 5.1 Inclusive ISO/TS 22003:2013
ISO 22000:2018 ISO/TS 22002-1:2009 Inclusive additional FSSC 22000 requirements version 5	K Production of food and feed additives, vitamins, minerals, bio-cultures, flavourings, enzymes and processing aids, (Excluded: pesticides, drugs, fertilizers, cleaning agents)	Edition 5.1 Inclusive ISO/TS 22003:2013
ISO 13485:2016	NON-ACTIVE MEDICAL DEVICES	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
	General non-active, non-im- plantable medical devices	
	Non-active devices for anaesthesia emergency and intensive care	
	Non-active devices for injection, infusion, transfusion and dialysis	Limitations see below
	Non-active orthopaedic and rehabilitation devices	
	Non-active medical devices with measuring function	
	Non-active ophthalmologic devices	
	Non-active instruments	
	Non-active medical devices for disinfecting, cleaning, rinsing	
	Devices for wound care	
	Bandages and wound dressings	
	Suture material and clamps	
	Other medical devices for wound care	
	Non-active dental devices and accessories	
ISO 13485:2016	Non-active dental devices/equip- ment and instruments	
	Dental materials	
	Dental implants	

07.03.2024 / BN asa/sts 0013scesmvz en.docx 8/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

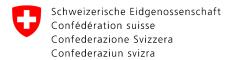
Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
	Non-active medical devices other than specified in table 1.1	
	To be specified in advance	
	ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES	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
	General active medical devices	
	Active surgical devices	
	Active dental devices	
	Active devices for disinfection and sterilisation	
	STERILIZATION METHODS FOR MEDICAL DEVICES	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
	Moist heat	
	Disposable new and reusable devices or part of it	
	Aseptic processing	
	Disposable new and reusable devices or parts of it	
	Hydrogen peroxide	
	Disposable new and reusable devices or parts of it	
	PARTS AND SERVICES	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
ISO 13485:2016	Raw materials	
	Raw metals, plastic, wood, ceramic	

07.03.2024 / BN asa/sts 0013scesmvz en.docx 9/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

Swiss Accreditation Service SAS

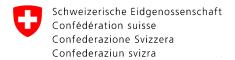
SCESm Directory

Accreditation number: SCESm 0013

Standards	Approved technical scopes	Remarks
	Components	
	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic	
	Subassemblies	
	Electronic and mechanical subas- semblies, made to drawings and/or work instructions area	
	Calibration services	
	Verification/confirmation services for measuring instruments, tools and test fixtures	
	Distribution services	
	Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices	
	Maintenance services	
	Electrical or mechanical repair services	
	Facility cleaning and maintenance services	
	Uniform cleaning and testing of ESD smocks	
	Transportation services	
	Trucking, shipping	
	Air transportation service in general	
	Other services	
	Consulting services related to medical devices	
	Packaging services	

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

07.03.2024 / BN asa/sts 0013scesmvz en.docx 10/11



Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0013

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

Abbreviation	Signification
eduQua	Certification body for quality management system in adult training institutes, Ref. www.eduqua.ch
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
scc	Safety Certificate Contractors, Ref: http://www.scc-sekretariat.de/

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07.03.2024 / BN asa/sts 0013scesmvz en.docx 11/11