



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
Initial accreditation: 16.03.1994
Current accreditation: 01.07.2019 to 30.06.2024
Scope of accreditation see: www.sas.admin.ch
(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	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



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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



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Standards	Approved technical scopes	Remarks
ISO 14001:2015	Food products, beverages and tobacco	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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	Other services	35



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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 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
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	Pharmaceuticals	13
	Rubber and plastic products	14
	Non-metallic mineral products	15
	Concrete, cement, lime, plaster etc.	16
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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
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	Public administration	36
	Education	37
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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	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
SN EN ISO 3834-2:2006 (ISO 3834-2:2005)	Quality requirements for welding, Comprehensive quality requirements	
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 according to the standard eduQua:2012 keep their validity until 30.06.2025, at the latest
IN-Qualis:2018	Work integration	



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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 vessels 2014/29/EU of 02/26/2014	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. 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
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
Ordinance on the safety of lifts, SR 930.112 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 XI (Module H1) Explicitly excluded are design examinations according to Lift Safety Directive, Annex XI (3.3)
SCC ISO/IEC 20000-1:2018	Safety Certificate Contractors 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



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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) Cluster 2. Food and Feed Processing (C + D) 4. Retail, transport and storage (F + G) 5. Auxiliary Services (I) 6. (Bio) Chemicals (K)	The certification body satisfies the requirements according to ISO/TS 22003:2013 for the sectors C Food Manufacturing D Animal Feed Production F Distribution G Provision of Transport and Storage Services I Production of Food Packaging and Packaging Materials 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: 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	Edition 5.1 Including ISO/TS 22003:2013
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

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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, (<u>Excluded</u> : pesticides, drugs, fertilizers, cleaning agents)	Edition 5.1 Inclusive ISO/TS 22003:2013
ISO 13485:2016	<p>NON-ACTIVE MEDICAL DEVICES</p> <p>General non-active, non-implantable medical devices</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>Devices for wound care</p> <p>Bandages and wound dressings</p> <p>Suture material and clamps</p> <p>Other medical devices for wound care</p> <p>Non-active dental devices and accessories</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>
ISO 13485:2016	<p>Non-active dental devices/equipment and instruments</p> <p>Dental materials</p> <p>Dental implants</p>	



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ISO 13485:2016	Non-active medical devices other than specified in table 1.1 To be specified in advance ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES General active medical devices Active surgical devices Active dental devices Active devices for disinfection and sterilisation STERILIZATION METHODS FOR MEDICAL DEVICES 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 1.2 Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives 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
	Raw materials Raw metals, plastic, wood, ceramic	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



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	<p>Components</p> <p>Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic</p> <p>Subassemblies</p> <p>Electronic and mechanical subassemblies, made to drawings and/or work instructions area</p> <p>Calibration services</p> <p>Verification/confirmation services for measuring instruments, tools and test fixtures</p> <p>Distribution services</p> <p>Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices</p> <p>Maintenance services</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>Transportation services</p> <p>Trucking, shipping</p> <p>Air transportation service in general</p> <p>Other services</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.



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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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