



SCESm Directory

Accreditation number: **SCESm 0001**

International standard: ISO/IEC 17021-1:2015

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

Swiss Association for Quality
and Management Systems
(SQS)

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Initial accreditation:

21.07.1992

Current accreditation:

12.08.2022 to 11.08.2027

Scope of accreditation see:

www.sas.admin.ch
(Accredited bodies)

Scope of accreditation as of 12.09.2022

Certification body for management systems in the domain 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	



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Standards	Approved technical scopes	Remarks	
ISO 9001:2015	Manufacture of coke and refined petroleum products	10	
	Manufacture and processing of nuclear fuel	11	
	Chemicals, chemical products and fibres	12	
	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	Code NACE 35-12 pleasure and sporting boats
	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		



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Standards	Approved technical scopes	Remarks
ISO 9001:2015	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
	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
	Manufacture and processing of nuclear fuel	11
	Chemicals, chemical products and fibres	12
	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	



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ISO 14001:2015	Machinery and equipment	18
	Electrical and optical equipment	19
	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
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Other social services	39	
ISO 45001:2018		IAF Code
	Mining and quarrying	2
	Food products, beverages and tobacco	3
	Textiles and textile products	4



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Standards	Approved technical scopes	Remarks
ISO 45001:2018	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
	Production et traitement de produits d'industries nucléaires	11
	Chemicals, chemical products and fibres	12
	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
	Aerospace	21
	Other transport equipment	22
	Manufacturing not elsewhere classified	23
	Recycling	24
	Electricity supply	25
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ISO 45001:2018	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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ISO 50001:2018	Energy Management Systems - Industry – light to medium - Industry – heavy - Mining - Energy supply - Buildings - Building complexes - Transport - Agriculture	Fulfils the requirements of the standard ISO 50003:2014.
AQAP 2110: 2016	Same scope as ISO 9001:2015	Only in combination with a certification according to ISO 9001
NATO-QS-Requirements		
eduQua:2021 eduQua:2012	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
ISO 21001:2018	Provider of learning services for non-formal education and training	
IN-Qualis 2018	Measures of the employment market	
ISO 22000:2018	Food safety management systems for the clusters (according to ISO/TS 22003)	Fulfils the requirements of ISO/TS 22003:2013 for the sectors



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ISO 22000:2018	Cluster 2. Food and Feed Processing (C + D) 3. Catering (E) 4. Retail, transport and storage (F + G) 5. Auxiliary Services (H + I + J) 6. (Bio) Chemicals (K)	C Food Manufacturing D Animal Feed Production E Catering F Distribution G Provision of Transport and Storage Services H Services I Production of Food Packaging and Packaging Materials J Equipment Manufacturing 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) DIIa 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 DIIb Production of Pet Food for other pet than dog and cat	Edition 5.1 Inclusive ISO/TS 22003:2013
ISO 22000:2018 ISO/TS 22002-2:2013 Inclusive additional FSSC 22000 requirements version 5	E Catering	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	Edition 5.1 Inclusive ISO/TS 22003:2013



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ISO 22000:2018 ISO/TS 22002-4:2013 Inclusive additional FSSC 22000 requirements version 45	GII Provision of Transport and Storage Services for Ambient Stable Food and Feed. 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
FAMI-QS: 2018 Version 6, October 2018 FAMI-QS Code of Practice – Quality and Safety System for Specialty Feed Ingredients	Production (Bioprocess – Chemical – Mixing – Formulating – Mining – Extraction) and Trade of Specialty Feed Ingredients DI: for products fed directly to the animal and/or delivered to the farm K: products not given directly to the animals and/or not sold directly to the farm FI: when Operator trade their own products FII: when Operator trade products not produced by themselves	Including ISO/TS 22003:2013
DIN EN 15593:2008	Packaging - Management of hygiene in the production of packaging for foodstuffs. Requirements.	
ISO/IEC 20000-1:2018	IT Service Management	Fulfils the requirements of the standard ISO/IEC 20000-6:2017
ISO/IEC 27001:2013	Information Security Management Systems ISMS	Fulfils the requirements of the standard ISO/IEC 27006:2015/Amd. 1:2020
ODPC - (SR 235.13) including the directives of the Swiss Federal Data Protection and Information Commissioner (FDPIC) with respect to the minimum requirements for a data protection management system and its Appendix (Guidelines for the Management of Data Protection)	Data Protection Management Systems (DPMS) in accordance with Article 4 ODPC: Certification of Organization and Procedures	Based on Swiss Federal Data Protection Law (SR 235.1) including special legal data protection regulations Ordinance on the Swiss Federal Data Protection Law (SR 235.11)



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EN 9100:2018 AS 9100D	Management Systems for Aero-space industry	Fulfils the requirements of EN 9104-001:2013 and since the 25.07.2017, the body satisfies the requirements of AS 9101F.
EN 9120:2018 AS 9120B	Management Systems for Aero-space industry / requirements for stockist distributors	Fulfils the requirements of EN 9104-001:2013 and since the 25.07.2017, the body satisfies the requirements of AS 9101F.
SN EN ISO 3834-2:2021 SN EN ISO 3834-2:2006 (ISO 3834-2:2005)	Quality requirements for welding, Comprehensive quality requirements	Combined with a certification based on ISO 9001:2015 (Replaces EN 729-2) 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 3834-3:2021 SN EN ISO 3834-3:2006 (ISO 3834-3:2005)	Standard quality requirements	
SN EN ISO 3834-4:2021 SN EN ISO 3834-4:2006 (ISO 3834-4:2005)	Elementary quality requirements	
SR 930.114 Regulation on the safety of pressure equipment (Pressure Equipment Ordinance) (EC Pressure Equipment Directive 2014/68/EU)	Complete quality assurance without draft examination and surveillance of the final verification Annex III – module H	Notified Body EU identification number NB 1250 according to 2014/68/EU Indication The modules B, C2, D1, D, E1, E, F, G and H1 are covered by SCESp 0049.



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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")	Lifts Annex XI (Module H1)	Explicitly excluded are design examinations according to Lift Safety Directive, Annex XI (3.3)
ISO 15378:2017	Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)	Certification combined with ISO 9001:2015
ISO 15378:2017	Medical Devices and related Processes	Only certification according to standard ISO 13485 without requirements of TPA, MDO, 93/42/EEC respectively Regulation (EU) 2017/745
SN EN ISO 13485:2016	NON-ACTIVE MEDICAL DEVICES General non-active non-implantable medical devices Non-active devices for anaesthesia, emergency and intensive care Non-active devices for injection, infusion, transfusion and dialysis Non-active orthopedic 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 Non-active implants Non-active orthopedic implants Non-active functional implants	Technical scope according to IAF MD 8:2017 - Table 1.1 Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives



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SN EN ISO 13485:2016	<p>Non-active soft tissue implant</p> <p>Devices for wound care</p> <p>Bandages and wound dressing</p> <p>Suture material and clamps</p> <p>Other medical devices for wound care</p> <p>Non-active dental devices and accessories</p> <p>Non-active dental devices / equipment and instruments</p> <p>Dental materials</p> <p>Dental implants</p> <p>Non-active medical devices other than specified in table 1.1</p> <p>To be specified in advance</p> <p>ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES</p> <p>General active medical devices</p> <p>Devices for extra-corporal circulation, infusion and haemopheresis</p> <p>Devices for stimulation or inhibition</p> <p>Active surgical devices</p> <p>Active ophthalmologic devices</p> <p>Active dental devices</p> <p>Active devices for disinfection and sterilization</p> <p>Software</p> <p>Medical gas supply systems and parts thereof</p>	<p>Technical scope according to IAF MD 8:2017 - Table 1.2</p> <p>Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives</p> <p>Includes products listed in the table 1.2 that incorporate / use software or are controlled by software.</p>



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<p>SN EN ISO 13485:2016</p>	<p>Devices for imaging Devices utilizing non-ionizing radiation</p> <p>Monitoring devices Monitoring devices of non-vital physiological parameters Monitoring devices of vital physiological parameters</p> <p>Devices for radiation therapy and thermo therapy Devices for (extra corporal) shock-wave therapy (lithotripsy)</p> <p>Active (non-implantable) medical devices other than specified in table 1.2: Medical devices referencing the Directive 2006/42/EC on machinery</p> <p>STERILIZATION METHODS FOR MEDICAL DEVICES</p> <p>Moist heat Disposable new and reusable devices or part of it</p> <p>Aseptic processing Disposable new and reusable devices or parts of it</p> <p>Ethylene oxide gas Disposable new and reusable devices or parts of it</p> <p>Radiation sterilization (e.g. gamma, x-ray, electron beam) Disposable new and reusable devices or parts of it</p>	<p>Together with appropriate knowledge of attributed IAF codes in the product category</p> <p>Technical scope according to IAF MD 8:2017 - Table 1.5 Mainly relevant for MS of specialized sterilizers / contractors and/or manufacturers of medical devices and / or their legal representatives</p>



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<p>SN EN ISO 13485:2016</p>	<p>DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES</p> <p>Medical devices incorporating medicinal substances Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed</p> <p>PARTS AND SERVICES</p> <p>Raw materials Raw metals, plastic, wood, ceramic</p> <p>Components Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic</p> <p>Subassemblies Electronic and mechanical subassemblies, made to drawings and/or work instructions area</p> <p>Calibration services Verification/confirmation services for measuring instruments, tools and test fixtures</p>	<p>Technical scope according to IAF MD 8:2017 - Table 1.6 Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives.</p> <p>Technical scope according to IAF MD 8: 2017 – Table 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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SN EN ISO 13485:2016	<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.

Abbreviation	Signification
93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical device
2006/42/EC	Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC
APEQ	Agence pour la promotion et l'évaluation de la qualité dans les institutions sanitaires
eduQua	Certification body for quality management system in adult training institutes. Ref. www.eduqua.ch
EnMS	Energy Management System
ESD	Electrostatic discharges
(EU) 2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; 5 May 2017



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Abbreviation	Signification
FAMI-QS	FAMI-QS European Feed Additives and Premixtures Quality System, Brussels, actual version of the standard document, http://www.fami-qs.org/
IAF Code	IAF ID1, Informative Document for QMS and EMS Scopes of Accreditation
MDO	Swiss Medical Device Ordinance, SR 812.213
ODPC	Ordinance on Date Protection Certification, SR 235.13
SVOAM	Swiss association of the organizers of measures of the employment market

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