

Federal Department of Economic Affairs, Education and Research EAER

State Secretariat for Economic Affairs SECO

Swiss Accreditation Service SAS

SCESm Directory

Accreditation number: SCESm 0047

International standard: ISO/IEC 17021-1:2015

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

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Initial accreditation: 24.03.1998

Current accreditation: 23.03.2025 to 22.03.2030

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

(Accredited bodies)

Scope of accreditation as of 23.03.2025

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

Standards	Approved technical scopes	Remarks
ISO 9001:2015		
ISO 14001:2015		
		IAF Code
	Mining and quarrying	2
	Food products, beverages and tobacco	3
	Textiles and textile products	4 (only for ISO 9001:2015)
	Publishing companies	8
	Printing companies	9
	Chemicals, chemical products and fibres	12
	Pharmaceuticals	13 (only for ISO 9001:2015)
	Rubber and plastic products	14
	Concrete, cement, lime, plaster etc.	16

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Standards	Approved technical scopes	Remarks
	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
	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 intrmediation, real estate, renting	32
	Information technology	33
	Engineering services	34
	Other services	35
	Public administratioin	36
	Education	37
	Health and social work	38
	Other social services	39
ISO 45001:2018	Occupational health and safety management systems	
		IAF Code
	Food products, beverages and tobacco	3
	Publishing companies	8
	Chemicals, chemical products and fibres	12
	Rubber and plastic products	14
	Basic metals and fabricated metal products	17
	Machinery and equipment	18

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Standards	Approved technical scopes	Remarks
	Electrical and optical equipment	19
	Other transport equipment	22
	Manufacturing not elsewhere classified	23
	Recycling	24
	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 intrmediation, real estate, renting	32
	Information technology	33
	Engineering services	34
	Other services	35
	Education	37
	Health and social work	38
	Other social services	39
SN EN ISO 3834-2:2021	Quality requirements for welding	Combined with a certification based on ISO 9001 (Replaces EN 729-2)
ISO 22000:2018	Food safety management systems Cluster / categories 2 - 6	Fulfils the requirements of ISO/TS 22003:2013 for the sectors Existing certificates remain valid until 30.06.2025 at the latest
	2. Food and Feed Processing (C + D)	C Food Manufacturing D Animal Feed Production
	3. Catering (E)	E Catering
	4. Retail, transport and storage (F + G)	F Distribution G Provision of Transport and Storage Services

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Standards	Approved technical scopes	Remarks
	5. Auxiliary Services (H + I + J)	H Services I Production of Food Packaging and Packaging Materials J Equipment Manufacturing
	6. (Bio) Chemicals (K)	K Production of chemical and biochemical products
ISO 22000:2018	Food safety management systems for the clusters (according to ISO 22003-1:2022)	Fulfils the requirements of ISO 22003-1:2022 for the sectors
	(Category B; only BIII – Pre- process handling of plant products)	B Farming or handling of plants
	Processing food for humans and animals (C + D)	C Food, ingredient and pet food processing D Feed and animal food processing
	3. Catering/food service (E)	E Catering/food services
	4. Retail, transport and storage (F + G)	F Trading, retail and e-commerce G Transport and Storage Services
	5. Auxiliary Services (H)	H Services
	6. Packaging material (I)	I Production of Packaging Materials
	7. Auxiliary equipment (J)	J Equipment
	8. Bio/chemical (K)	K Chemical and bio-chemical
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 50003:2021
	Medical Devices and related Processes	Only certification according to standard ISO 13485 without re- quirements of TPA, MDO, 93/42/EEC respectively Regulation (EU) 2017/745

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Standards	Approved technical scopes	Remarks
SN EN ISO 13485:2016	NON-ACTIVE MEDICAL DEVICES	Technical scope according to IAF MD 8:2023 - Table 1.1 Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives
	General non-active non-im-	and the second s
	plantable medical devices Non-active devices for anaesthe-	
	sia, 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	
	Contraceptive medical devices	
	Non-active medical devices for	
	disinfecting, cleaning, rinsing	
	Non-active medical devices for ingestion	
	Non-active implants	
	Non-active cardiovascular implants	
	Non-active orthopedic implants	
	Non-active functional implants	
	Devices for wound care	
	Bandages and wound dressing	
	Suture material and clamps Other medical devices for wound	
	care	
	Non-active dental devices and accessories	
	Non-active dental devices /	
	equipment and instruments	
	Dental materials	
	Dental implants Non-active medical devices	
	other than specified in table 1.1:	
	To be defined in advance	
SN EN ISO 13485:2016	ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES	Technical scope according to IAF MD 8:2023 - Table 1.2
	General active medical devices	Mainly relevant for MS of manu-
	Scholal active medical devices	facturers of medical devices and/or their legal representatives

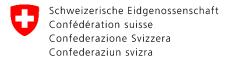
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Standards	Approved technical scopes	Remarks
	Devices for extra-corporal circulation, infusion and haemopheresis Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anesthesia Devices for stimulation or inhibition Active surgical devices Active dental devices Active rehabilitation devices and active prostheses Active devices for patient posi-	
	tioning and transport Software	Includes products listed in the table 1.2 that incorporate / use software or are controlled by software.
	Devices for imaging Devices utilizing ionizing radiation Devices utilizing non-ionizing radiation Monitoring devices Monitoring devices of non-vital physiological parameters Monitoring devices of vital physiological parameters Devices for radiation therapy and thermos therapy Devices utilizing non-ionizing radiation	
	Active (non-implantable) medical devices other than specified in table 1.2: Medical devices referencing the Directive 2006/42/EC on machinery STERILIZATION METHODS FOR MEDICAL DEVICES	Together with appropriate know-ledge of attributed IAF codes in the product category Technical scope according to IAF MD 8:2023 - Table 1.5 Mainly relevant for MS of specialized sterilizers / contractors and/or manufacturers of medical devices and / or their legal representatives
	Moist heat Aseptic processing Low temperature steam and formaldehyde sterilization Sterilization with hydrogen	



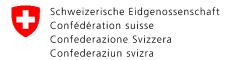
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Standards	Approved technical scopes	Remarks
	Peroxide	
SN EN ISO 13485:2016	DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES	Technical scope according to IAF MD 8:2023 - Table 1.6 Mainly relevant for MS of manu facturers of medical devices and/or their legal representatives
	Medical devices incorporating medicinal substances	
	Medical devices utilizing bio- logical active coatings and/or materials or being wholly or mainly absorbed	Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives
SN EN ISO 13485:2016	PARTS AND SERVICES	Technical scope according to IAF MD 8: 2023 – Table 1.7 Mainly relevant for MS of manu facturers and/or sub-assemblers and/or distributors of medical devices Together with appropriate knowledge of the relevant IAF Codes in the product category
	Raw materials	
	Raw metals, plastic, wood, ceramic	
	Components	
	Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic	
	Subassemblies Electronic and mechanical subassemblies, made to drawings and/or work instructions area	
	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 mainte- nance services	
	Uniform cleaning and testing of ESD smocks	
	Transportation services	
	Trucking, shipping Air transportation service in general	



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Standards	Approved technical scopes	Remarks
	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.

Abbreviation	Signification
(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
EnMS	Energy Management System
ESD	Electrostatic discharges
IAF Code	See document IAF ID1: 2014 (www.iaf.nu)
MDO	Swiss Medical Device Ordinance, SR 812.213
TPA	Swiss Therapeutic Products Act, SR 812.21
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

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