Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

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:	24.03.2020 to 23.03.2025
Scope of accreditation see:	www.sas.admin.ch (Accredited bodies)

Scope of accreditation as of 05.08.2021

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
	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 BS OHSAS 18001:2007	Occupational health and safety management systems	Already granted certificates according to the standard BS OHSAS 18001:2007 keep their validity until 11.03.2021, at the latest.
		IAF Code
	Food products, beverages and tobacco	3
	Publishing companies	8
	Chemicals, chemical products and fibres	12
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SN EN ISO 3834-2:2006 (ISO 3834-2:2005)	Quality requirements for welding, Comprehensive quality require-ments	Combined with a certification based on ISO 9001 (Replaces EN 729-2)
ISO 22000:2018 ISO 22000:2005	Food safety management systems Cluster / categories 2 - 6	Fulfils the requirements of ISO/TS 22003:2013 for the sectors (Already granted certificates ac-cording to the standard ISO 22000:2005 keep their validity until 29.06.2021 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 50001:2018 ISO 50001:2011	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 Already granted certificates according to the standard ISO 50001:2011 keep their validity until 31.08.2021, at the latest.
SN EN ISO 13485:2016	**Medical Devices and related Processes** **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 Contraceptive medical devices Non-active medical devices for disinfecting, cleaning, rinsing Non-active medical devices for ingestion	Only certification according to standard ISO 13485 without requirements of TPA, MDO, 93/42/EEC respectively Regulation (EU) 2017/745 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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Standards	Approved technical scopes	Remarks
	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 8:2017 - Table 1.2**
	General active medical devices	Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives
	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 positioning 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	

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Standards	Approved technical scopes	Remarks
	Devices utilizing non-ionizing radiation **Monitoring devices** Monitoring devices of non-vital physiological parameters Monitoring devices of vital physiological parameters	
	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	Together with appropriate knowledge of attributed IAF codes in the product category
	STERILIZATION METHODS FOR MEDICAL DEVICES	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
	Moist heat Disposable new and reusable devices or part of it **Aseptic processing** Disposable new and reusable devices or parts of it	
SN EN ISO 13485:2016	**DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES**	Technical scope according to IAF MD 8:2017 - 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 biological 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: 2017 – 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

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Standards	Approved technical scopes	Remarks
	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 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.

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

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Abbreviation	Signification
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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