



## 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: [www.sas.admin.ch](http://www.sas.admin.ch)  
(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
ISO 45001:2018	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 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
	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
SN EN ISO 3834-2:2021	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 intermediation, real estate, renting	32
	Information technology	33
	Engineering services	34
	Other services	35
	Education	37
	Health and social work	38
	Other social services	39
	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
ISO 22000:2018	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
	Food safety management systems for the clusters (according to ISO 22003-1:2022)	Fulfil the requirements of ISO 22003-1:2022 for the sectors
	1. – (Category B; only BIII – Pre-process handling of plant products)	B Farming or handling of plants
	2. 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
ISO 50001:2018	8. Bio/chemical (K)	K Chemical and bio-chemical
	Energy Management Systems - Industry – light to medium - Industry – heavy - Mining - Energy supply - Buildings - Building complexes - Transport - Agriculture  <b>Medical Devices and related Processes</b>	Fulfil the requirements of the standard ISO 50003:2021  Only certification according to standard ISO 13485 without requirements 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	<b>NON-ACTIVE MEDICAL DEVICES</b>  <b>General non-active non-implantable medical devices</b> 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 <b>Non-active implants</b> Non-active cardiovascular implants Non-active orthopedic implants Non-active functional implants <b>Devices for wound care</b> Bandages and wound dressing Suture material and clamps Other medical devices for wound care <b>Non-active dental devices and accessories</b> Non-active dental devices / equipment and instruments Dental materials Dental implants <b>Non-active medical devices other than specified in table 1.1:</b> To be defined in advance	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
SN EN ISO 13485:2016	<b>ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES</b> <b>General active medical devices</b>	<b>Technical scope according to IAF MD 8:2023 - Table 1.2</b> Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives



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



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Standards	Approved technical scopes	Remarks
SN EN ISO 13485:2016	<b>Peroxide DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES</b>	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
SN EN ISO 13485:2016	<b>Medical devices incorporating medicinal substances Medical devices utilizing bio- logical active coatings and/or materials or being wholly or mainly absorbed PARTS AND SERVICES</b>	Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives  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 de- vices Together with appropriate knowledge of the relevant IAF Codes in the product category
	<b>Raw materials</b> Raw metals, plastic, wood, ce- ramic <b>Components</b> Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic <b>Subassemblies</b> Electronic and mechanical subas- semblies, made to drawings and/or work instructions area <b>Distribution services</b> Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices <b>Maintenance services</b> Electrical or mechanical repair services Facility cleaning and mainte- nance services Uniform cleaning and testing of ESD smocks <b>Transportation services</b> Trucking, shipping Air transportation service in gen- eral	

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	<b>Other services</b> 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 ( <a href="http://www.iaf.nu">www.iaf.nu</a> )
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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