



SCESm Directory

Accreditation number: **SCESm 0003**

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

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Initial accreditation: 21.07.1992
Current accreditation: 30.07.2022 to 29.07.2027
Scope of accreditation see: www.sas.admin.ch
(Accredited bodies)

Scope of accreditation as of 30.07.2022

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

Standards	Approved technical scopes	Remarks
ISO 9001:2015	Quality management systems	IAF Code
	Agriculture, fishing	1
	Mining and quarrying	2
	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
	Non-metallic mineral products	15
	Concrete, cement, lime, plaster etc.	16
Basic metals and fabricated metal products	17	



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Standards	Approved technical scopes	Remarks	
ISO 14001:2015	Machinery and equipment	18	
	Electrical and optical equipment	19	
	Shipbuilding	20	
	Machinery and equipment	22	
	Electrical and optical equipment	23	
	Shipbuilding	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	
	Environmental management systems	IAF Code	
	Agriculture, fishing	1	
	Mining and quarrying	2	
	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		
Chemical, chemical products and fibres	12		
Pharmaceuticals	13		



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Standards	Approved technical scopes	Remarks
ISO 45001:2018	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
	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
	Other social services	39
	Occupational health and safety management systems	IAF Code
	Mining and quarrying	2
	Food products, beverages and tobacco	3
	Pulp, paper and paper products	7
	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	
EN ISO 13485:2016	Electrical and optical equipment	19	
	Manufacturing not elsewhere classified	23	
	Recycling	24	
	Construction	28	
	Hotels and restaurants	30	
	Transport, storage and communication	31	
	Financial intermediation, real estate, renting	32	
	Engineering services	34	
	Other services	35	
	Medical devices - Quality management systems - Requirements for regulatory purposes		Only certification of quality management systems; no procedures for assessing the conformity; no label according to SR 946.512
	Non-active medical devices:		
	Non-active devices for anaesthesia, emergency and intensive caresoft tissue implants		
	Medical devices and related processes		Only certification of quality management systems; according to the ISO 13485 standard, no procedures for assessing conformity; no designation according to SR 946.512
	NON-ACTIVE MEDICAL DEVICES		Technical scope according to IAF MD 8:2023 - Table 1.1.
	General non-active, non-implantable medical devices		Mainly relevant for MS of medical device manufacturers and/or their legal representatives.
Non-active devices for anesthesia, emergency medicine and intensive care medicine			
Non-active devices for orthopedics and rehabilitation			
Non-active medical devices with a measuring function			
Non-active ophthalmic devices			
Non-active medical instruments			
Non-active medical devices for disinfection, cleaning and rinsing			



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Standards	Approved technical scopes	Remarks
	<p>Non-active implants</p> <p>Non-active orthopedic implants</p> <p>Wound care products</p> <p>Dressings and wound dressings</p> <p>Suture and staple material</p> <p>Other medical devices for wound care</p> <p>Non-active dental products and accessories</p> <p>Non-active dental products, equipment and instruments</p> <p>Dental materials</p> <p>Dental implants</p> <p>Patient positioning and transport</p> <p>Other non-active medical devices not listed above</p> <p>ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES</p> <p>General active medical devices</p> <p>Active surgical devices</p> <p>Active dental equipment</p> <p>Active patient positioning and transport facilities</p> <p>Active (non-implantable) medical devices not listed above</p> <p>Medical devices according to the 2006/42/EG directive on machines</p>	<p>Only certification of quality management systems; according to the ISO 13485 standard, no procedures for assessing conformity; no designation according to SR 946.512</p> <p>Technical scope according to IAF MD 8:2023 - Table 1.1. Mainly relevant for MS of medical device manufacturers and/or their legal representatives.</p>



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Standards	Approved technical scopes	Remarks
	<p>PARTS AND SERVICES</p> <p>Components Electrical components, connectors, molded raw materials, machined raw materials and molded plastics</p> <p>Assembly services/Module Electronic and mechanical assemblies, made according to drawings and/or work instructions</p> <p>Distribution Services Distributors who offer storage and delivery of medical devices and do not act as a "legal manufacturer" of medical devices</p> <p>Maintenance services Electrical or mechanical repair services Building cleaning and maintenance services Uniform cleaning and testing of ESD smocks</p> <p>Transportation services Freight forwarders and shipping Air transport in general</p> <p>Other services Consulting services related to medical devices Packaging services</p>	<p>Technical scope according to IAF MD 8:2023 - Table 1.7. Mainly relevant for MS of manufacturers and/or sub-assemblers/subcontractors and/or distributors of medical devices and/or their legal representatives.</p>

In case of contradictions in the language versions of the directories, the German version shall apply.

Abbreviation	Signification
IAF Code	Economic Activity Code; see also IAF ID1, Informative Document for QMS and EMS Scopes of Accreditation

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