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

QS Zürich AG
P.O. Box 6335
8050 Zürich

QS Zürich AG
Branch Basel
Erlenstrasse 31
4106 Therwil

Head:	Lukas Beljean
Responsible for MS:	Lukas Beljean
Telephone:	+41 44 35 04 665
E-Mail:	qs-zuerich@quality-service.ch
Internet:	www.quality-service.ch
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 21.01.2022

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
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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	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
	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
	5. Auxiliary Services (H + I + J)	H Services I Production of Food Packaging and Packaging Materials J Equipment Manufacturing

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Standards	Approved technical scopes	Remarks
	6. (Bio) Chemicals (K)	K Production of chemical and biochemical products
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
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 **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	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
SN EN ISO 13485:2016	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 **ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES** **General active medical devices** 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	**Technical scope according to IAF MD 8:2017 - Table 1.2** Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives
	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 utilizing non-ionizing radiation **Active (non-implantable) medical devices other than specified in table 1.2:**	**Includes products listed in the table 1.2 that incorporate / use software or are controlled by software.**

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Standards	Approved technical scopes	Remarks
	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
	Raw materials Raw metals, plastic, wood, ceramic	
	Components Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic	

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Standards	Approved technical scopes	Remarks
	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
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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