



SCESm Directory

Accreditation number: SCESm 0001

International standard: ISO/IEC 17021-1:2015

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

Swiss Association for Quality
and Management Systems
(SQS)

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Initial accreditation:

21.07.1992

Current accreditation:

12.08.2017 to 11.08.2022

Scope of accreditation see:

www.sas.admin.ch
(Accredited bodies)

Scope of accreditation as of 30.03.2021

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

| Standards | Approved technical scopes | Remarks |
|--------------------|--------------------------------------|----------|
| ISO 9001:2015 | | IAF Code |
| | Agriculture, fishing | 1 |
| | Mining and quarrying | 2 |
| | Food products, beverages and tobacco | 3 |
| | Textiles and textile products | 4 |
| | Leather and leather products | 5 |
| | Wood and wood products | 6 |
| | Pulp, paper and paper products | 7 |
| | Publishing companies | 8 |
| Printing companies | 9 | |



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| Standards | Approved technical scopes | Remarks | |
|--|--|---------|---|
| ISO 9001:2015 | Manufacture of coke and refined petroleum products | 10 | |
| | Manufacture and processing of nuclear fuel | 11 | |
| | 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 | |
| | Machinery and equipment | 18 | |
| | Electrical and optical equipment | 19 | |
| | Shipbuilding | 20 | Code NACE 35-12 pleasure and sporting boats |
| | Aerospace | 21 | |
| | 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 | | |



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| Standards | Approved technical scopes | Remarks |
|--|--|----------|
| ISO 9001:2015 | Information technology | 33 |
| | Engineering services | 34 |
| | Other services | 35 |
| | Public administration | 36 |
| | Education | 37 |
| | Health and social work | 38 |
| | Other social services | 39 |
| ISO 14001:2015 | | IAF Code |
| | Agriculture, fishing | 1 |
| | Mining and quarrying | 2 |
| | Food products, beverages and tobacco | 3 |
| | Textiles and textile products | 4 |
| | Leather and leather products | 5 |
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|---------------------------------------|--|--|---|
| ISO 14001:2015 | Machinery and equipment | 18 | |
| | Electrical and optical equipment | 19 | |
| | Shipbuilding | 20 | Code NACE 35-12 pleasure and sporting boats |
| | Aerospace | 21 | |
| | Other transport equipment | 22 | |
| | Manufacturing not elsewhere classified | 23 | |
| | Recycling | 24 | |
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| ISO 45001:2018 BS OHSAS 18001:2007 | | Already granted certificates according to the standard BS OHSAS 18001:2007 keep their validity until 11.03.2021, at the latest. | |



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| Standards | Approved technical scopes | Remarks |
|---------------------------------------|--|----------|
| ISO 45001:2018 BS OHSAS 18001:2007 | | IAF Code |
| | Mining and quarrying | 2 |
| | Food products, beverages and tobacco | 3 |
| | Textiles and textile products | 4 |
| | Leather and leather products | 5 |
| | Wood and wood products | 6 |
| | Pulp, paper and paper products | 7 |
| | Publishing companies | 8 |
| | Printing companies | 9 |
| | Manufacture of coke and refined petroleum products | 10 |
| | Production et traitement de produits d'industries nucléaires | 11 |
| | 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 |
| | Machinery and equipment | 18 |
| | Electrical and optical equipment | 19 |
| | Aerospace | 21 |
| | Other transport equipment | 22 |
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| Standards | Approved technical scopes | Remarks |
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| ISO 45001:2018 BS OHSAS 18001:2007 | Gas supply | 26 |
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| ISO 50001:2018 ISO 50001:2011 | Energy Management Systems - Industry – light to medium - Industry – heavy - Mining - Energy supply - Buildings - Building complexes - Transport - Agriculture | Already granted certificates according to the standard ISO 50001:2011 keep their validity until 31.08.2021. Fulfils the requirements of the standard ISO 50003:2014. |
| AQAP 2110: 2003 NATO-QS-Requirements | Same scope as ISO 9001:2015 | Only in combination with a certification according to ISO 9001 |
| eduQua:2012 | Education | Corresponds to IAF Code 37 |
| ISO 21001:2018 ISO 29990:2010 | Provider of learning services for non-formal education and training | Already granted certificates according to the standard ISO 29990:2010 keep their validity until 17.12.2021, at the latest. |



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| Standards | Approved technical scopes | Remarks |
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| IN-Qualis 2018 SVOAM-2010 | Measures of the employment market | Already granted certificates according to the standard SVOAM-2010 keep their validity until 28.02.2022, at the latest. |
| ISO 22000:2018 ISO 22000:2005 | Food safety management systems for the clusters (according to ISO/TS 22003) | Fulfils the requirements of ISO/TS 22003:2013 for the sectors Already granted certificates according to the standard ISO 22000:2005 keep their validity until 29.06.2021 |
| ISO 22000:2018 | Cluster 2. Food and Feed Processing (C + D) 3. Catering (E) 4. Retail, transport and storage (F + G) 5. Auxiliary Services (H + I + J) 6. (Bio) Chemicals (K) | C Food Manufacturing D Animal Feed Production E Catering F Distribution G Provision of Transport and Storage Services H Services I Production of Food Packaging and Packaging Materials J Equipment Manufacturing K Production of (Bio) Chemicals |
| ISO 22000:2018 ISO/TS 22002-1:2009 Inclusive additional FSSC 22000 requirements version 5 | Food Safety System Certification 22000 (FSSC 22000) for the categories: CI Processing of perishable animal products CII Processing of perishable plant products CIII Processing of perishable animal and plant products (mixed products) CIV Processing of ambient stable products (ambient temperature) DII Production of Pet Food for dog and cat | Edition 5.1 Including ISO/TS 22003:2013 Already granted certificates according to FSSC Version 4 keep their validity until 29.06.2021 |



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| <p>ISO 22000:2018 ISO/TS 22002-6:2016 Inclusive additional FSSC 22000 requirements version 5</p> | <p>DI Production of Feed DII Production of Pet Food for other pet than dog and cat</p> | <p>Edition 5.1 Inclusive ISO/TS 22003:2013</p> |
| <p>ISO 22000:2018 ISO/TS 22002-2:2013 Inclusive additional FSSC 22000 requirements version 5</p> | <p>E Catering</p> | <p>Edition 5.1 Inclusive ISO/TS 22003:2013</p> |
| <p>ISO 22000:2018 ISO/TS 22002-5:2019 Inclusive additional FSSC 22000 requirements version 5</p> | <p>GI Provision of Transport and Storage Services for Perishable Food and Feed GII Provision of Transport and Storage Services for Ambient Stable Food and Feed.</p> | <p>Edition 5.1 Inclusive ISO/TS 22003:2013</p> |
| <p>ISO 22000:2018 ISO/TS 22002-4:2013 Inclusive additional FSSC 22000 requirements version 5</p> | <p>I Production of Food Packaging and Packaging Material</p> | <p>Edition 5.1 Inclusive ISO/TS 22003:2013</p> |
| <p>ISO 22000:2018 ISO/TS 22002-1:2009 Inclusive additional FSSC 22000 requirements version 5</p> | <p>K Production of food and feed additives, vitamins, minerals, bio-cultures, flavourings, enzymes and processing aids, (Excluded: pesticides, drugs, fertilizers, cleaning agents)</p> | <p>Edition 5.1 Inclusive ISO/TS 22003:2013</p> |
| <p>FAMI-QS: 2018 Version 6, October 2018 FAMI-QS Code of Practice – Quality and Safety System for Specialty Feed Ingredients</p> | <p>Production (Bioprocess – Chemical – Mixing – Formulating – Mining – Extraction) and Trade of Specialty Feed Ingredients DI: for products fed directly to the animal and/or delivered to the farm K: products not given directly to the animals and/or not sold directly to the farm FI: when Operator trade their own products FII: when Operator trade products not produced by themselves</p> | <p>Including ISO/TS 22003:2013</p> |
| <p>FAMI-QS:2014 Version 5.1, February 2014 European Code of Practice for Feed Additives and Premixture Operators</p> | <p>Production of feed additives and premixes for the feed industry</p> | <p>Including ISO/TS 22003:2013 Already granted certificates according to the standard FAMI-QS:2014 keep their validity until 01.10.2020, at the latest.</p> |
| <p>DIN EN 15593:2008</p> | <p>Packaging - Management of hygiene in the production of packaging for foodstuffs. Requirements.</p> | |



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| ISO/IEC 20000-1:2018 ISO/IEC 20000-1:2011 | IT Service Management | Fulfils the requirements of the standard ISO/IEC 20000-6:2017 Already granted certificates according to the standard ISO/IEC 20000-1:2011 keep their validity until 30.09.2021, at the latest |
| ISO/IEC 27001:2013 | Information Security Management Systems ISMS | Fulfils the requirements of the standard ISO/IEC 27006:2015 |
| ODPC - (SR 235.13) including the directives of the Swiss Federal Data Protection and Information Commissioner (FDPIC) with respect to the minimum requirements for a data protection management system and its Appendix (Guidelines for the Management of Data Protection) | Data Protection Management Systems (DPMS) in accordance with Article 4 ODPC: Certification of Organization and Procedures | Based on Swiss Federal Data Protection Law (SR 235.1) including special legal data protection regulations Ordinance on the Swiss Federal Data Protection Law (SR 235.11) |
| EN 9100:2018 AS 9100D | Management Systems for Aerospace industry | Fulfils the requirements of EN 9104-001:2013 and since the 25.07.2017, the body satisfies the requirements of AS 9101F. |
| EN 9120:2018 AS 9120B | Management Systems for Aerospace industry / requirements for stockist distributors | Fulfils the requirements of EN 9104-001:2013 and since the 25.07.2017, the body satisfies the requirements of AS 9101F. |
| SN EN ISO 3834-2:2006 (ISO 3834-2:2005) | Quality requirements for welding, Comprehensive quality requirements | Combined with a certification based on ISO 9001:2015 (Replaces EN 729-2) |
| SN EN ISO 3834-3:2006 (ISO 3834-3:2005) | Standard quality requirements | |
| SN EN ISO 3834-4:2006 (ISO 3834-4:2005) | Elementary quality requirements | |
| SR 930.114 Regulation on the safety of pressure equipment (Pressure Equipment Ordinance) (EC Pressure Equipment Directive 2014/68/EU) | Quality assurance production Quality assurance products Quality assurance production Quality assurance products Complete quality assurance without draft examination and surveillance of the final verification | Annex III – module D1 Annex III – module E1 Annex III – module D Annex III – module E Annex III – module H Notified Body EU identification number NB 1250 according to 2014/68/EU |



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| <p>Ordinance on the safety of lifts, SR 930.112 Directive 2014/33/EU on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts ("Lift Safety Directive")</p> <p>ISO 15378:2017</p> | <p>Lifts</p> <p>Primary packaging materials for medicinal products — Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)</p> <p>Medical Devices and related Processes</p> | <p>Indication The modules A2, B, C2, F, G and module H1 without quality assurance are covered by SCESp 0049.</p> <p>Lift Safety Directive 2014/33/EU - Annex X (Module E) - Annex XI (Module H1) - Annex XII (Module D) Explicitly excluded are design examinations according to Lift Safety Directive, Annex XI (3.3)</p> <p>Certification combined with ISO 9001:2015</p> <p>Only certification according to standard ISO 13485 without requirements of TPA, MDO, 93/42/EEC respectively Regulation (EU) 2017/745</p> |
| <p>SN EN ISO 13485:2016</p> | <p>NON-ACTIVE MEDICAL DEVICES</p> <p>General non-active non-implantable medical devices</p> <p>Non-active devices for anaesthesia, emergency and intensive care</p> <p>Non-active devices for injection, infusion, transfusion and dialysis</p> <p>Non-active orthopedic and rehabilitation devices</p> <p>Non-active medical devices with measuring function</p> <p>Non-active ophthalmologic devices</p> <p>Non-active instruments</p> | <p>Technical scope according to IAF MD 8:2017 - Table 1.1</p> <p>Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives</p> |



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| <p>SN EN ISO 13485:2016</p> | <p>Non-active medical devices for disinfecting, cleaning, rinsing</p> <p>Non-active implants Non-active orthopedic implants Non-active functional implants Non-active soft tissue implant</p> <p>Devices for wound care Bandages and wound dressing Suture material and clamps Other medical devices for wound care</p> <p>Non-active dental devices and accessories Non-active dental devices / equipment and instruments Dental materials Dental implants</p> <p>Non-active medical devices other than specified in table 1.1: To be specified in advance</p> <p>ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES</p> <p>General active medical devices Devices for extra-corporal circulation, infusion and haemopheresis Devices for stimulation or inhibition Active surgical devices Active ophthalmologic devices Active dental devices Active devices for disinfection and sterilization Software Medical gas supply systems and parts thereof</p> | <p>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</p> <p>Includes products listed in the table 1.2 that incorporate / use software or are controlled by software.</p> |
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| <p>SN EN ISO 13485:2016</p> | <p>Devices for imaging</p> <p>Devices utilizing non-ionizing radiation</p> <p>Monitoring devices</p> <p>Monitoring devices of non-vital physiological parameters</p> <p>Monitoring devices of vital physiological parameters</p> <p>Devices for radiation therapy and thermo therapy</p> <p>Devices for (extra corporal) shock-wave therapy (lithotripsy)</p> <p>Active (non-implantable) medical devices other than specified in table 1.2:</p> <p>Medical devices referencing the Directive 2006/42/EC on machinery</p> <p>STERILIZATION METHODS FOR MEDICAL DEVICES</p> <p>Moist heat</p> <p>Disposable new and reusable devices or part of it</p> <p>Aseptic processing</p> <p>Disposable new and reusable devices or parts of it</p> | <p>Together with appropriate knowledge of attributed IAF codes in the product category</p> <p>Technical scope according to IAF MD 8:2017 - 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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| <p>SN EN ISO 13485:2016</p> | <p>Ethylene oxide gas</p> <p>Disposable new and reusable devices or parts of it</p> <p>Radiation sterilization (e.g. gamma, x-ray, electron beam)</p> <p>Disposable new and reusable devices or parts of it</p> <p>DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES</p> <p>Medical devices incorporating medicinal substances Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed</p> <p>PARTS AND SERVICES</p> <p>Raw materials</p> <p>Raw metals, plastic, wood, ceramic</p> <p>Components</p> <p>Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic</p> <p>Subassemblies</p> <p>Electronic and mechanical subassemblies, made to drawings and/or work instructions area</p> | <p>Technical scope according to IAF MD 8:2017 - Table 1.6 Mainly relevant for MS of manufacturers of medical devices and / or their legal representatives.</p> <p>Technical scope according to IAF MD 8: 2017 – Table 1.7 Mainly relevant for MS of manufacturers and / or sub-assemblers and / or distributors of medical devices Together with appropriate knowledge of the relevant IAF Codes in the corresponding product category</p> |
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| SN EN ISO 13485:2016 | <p>Calibration services</p> <p>Verification/confirmation services for measuring instruments, tools and test fixtures</p> <p>Distribution services</p> <p>Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices</p> <p>Maintenance services</p> <p>Electrical or mechanical repair services</p> <p>Facility cleaning and maintenance services</p> <p>Uniform cleaning and testing of ESD smocks</p> <p>Transportation services</p> <p>Trucking, shipping</p> <p>Air transportation service in general</p> <p>Other services</p> <p>Consulting services related to medical devices</p> <p>Packaging services</p> | |
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| Abbreviation | Signification |
|---------------|--|
| 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 |
| APEQ | Agence pour la promotion et l'évaluation de la qualité dans les institutions sanitaires |
| eduQua | Certification body for quality management system in adult training institutes. Ref. www.eduqua.ch |
| EnMS | Energy Management System |
| ESD | Electrostatic discharges |
| (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 |
| FAMI-QS | FAMI-QS European Feed Additives and Premixtures Quality System, Brussels, <u>actual version of the standard document</u> , http://www.fami-qs.org/ |
| IAF Code | IAF ID1, Informative Document for QMS and EMS Scopes of Accreditation |
| MDO | Swiss Medical Device Ordinance, SR 812.213 |
| ODPC | Ordinance on Date Protection Certification, SR 235.13 |
| SVOAM | Swiss association of the organizers of measures of the employment market |

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