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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| 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 08.02.2024

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

| Standards | Approved technical scopes | Remarks |
|---|---|---|
| ISO 9001:2015<br>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 |
| | Machinery and equipment | 18 |

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| Standards | Approved technical scopes | Remarks |
|---|---|---|
| | 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 |
| | Education | 37 |
| | Health and social work | 38 |
| | Other social services | 39 |
| SN EN ISO 3834-2:2021 | Quality requirements for welding | Combined with a certification based on ISO 9001<br>(Replaces EN 729-2) |
| SN EN ISO 3834-2:2006 | | Certificates according to the old series of standards SN EN ISO 3834-2:2006 or ISO 3834- 2:2005 remain valid until 30 April 2024 at the latest |
| ISO 22000:2018 | Food safety management systems<br>Cluster / categories 2 - 6 | Fulfils the requirements of ISO/TS 22003:2013 for the sectors<br>(Already granted certificates according to the standard ISO |
| | 2. Food and Feed Processing (C + D) | C Food Manufacturing<br>D Animal Feed Production |
| | 3. Catering (E) | E Catering |
| | 4. Retail, transport and storage (F + G) | F Distribution<br>G Provision of Transport and Storage Services |

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|---|---|---|
| | 5. Auxiliary Services (H + I + J) | H Services<br>I Production of Food Packaging and Packaging Materials<br>J Equipment Manufacturing |
| | 6. (Bio) Chemicals (K) | K Production of chemical and biochemical products |
| ISO 50001:2018 | Energy Management Systems<br>- Industry – light to medium<br>- Industry – heavy<br>- Mining<br>- Energy supply<br>- Buildings<br>- Building complexes<br>- Transport<br>- Agriculture | Fulfils the requirements of the standard<br>ISO 50003:2021 |
| SN EN ISO 13485:2016 | **Medical Devices and related Processes**<br><br>**NON-ACTIVE MEDICAL DEVICES**<br><br>**General non-active non-implantable medical devices**<br>Non-active devices for anaesthesia, emergency and intensive care<br>Non-active devices for injection, infusion, transfusion and dialysis<br>Non-active orthopedic and rehabilitation devices<br>Non-active medical devices with measuring function<br>Non-active ophthalmologic devices<br>Non-active instruments<br>Contraceptive medical devices<br>Non-active medical devices for disinfecting, cleaning, rinsing<br>Non-active medical devices for ingestion<br>**Non-active implants**<br>Non-active cardiovascular implants<br>Non-active orthopedic implants | Only certification according to standard ISO 13485 without requirements of TPA, MDO, 93/42/EEC respectively Regulation (EU) 2017/745<br>Technical scope according to IAF MD 8:2023 - Table 1.1<br>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 | Non-active functional implants<br>**Devices for wound care**<br>Bandages and wound dressing<br>Suture material and clamps<br>Other medical devices for wound care<br>**Non-active dental devices and accessories**<br>Non-active dental devices / equipment and instruments<br>Dental materials<br>Dental implants<br>**Non-active medical devices other than specified in table 1.1:**<br>To be defined in advance<br>**ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES**<br>**General active medical devices**<br>Devices for extra-corporal circulation, infusion and haemopheresis<br>Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anesthesia<br>Devices for stimulation or inhibition<br>Active surgical devices<br>Active dental devices<br>Active rehabilitation devices and active prostheses<br>Active devices for patient positioning and transport<br>Software<br>**Devices for imaging**<br>Devices utilizing ionizing radiation<br>Devices utilizing non-ionizing radiation<br>**Monitoring devices**<br>Monitoring devices of non-vital physiological parameters<br>Monitoring devices of vital physiological parameters | **Technical scope according to IAF MD 8:2023 - Table 1.2**<br>Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives<br>**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 |
|---|---|---|
| | **Devices for radiation therapy and thermos therapy**<br>Devices utilizing non-ionizing radiation<br>**Active (non-implantable) medical devices other than specified in table 1.2:**<br>Medical devices referencing the Directive 2006/42/EC on machinery<br>**STERILIZATION METHODS FOR MEDICAL DEVICES**<br><br><br><br><br>**Moist heat**<br>**Aseptic processing**<br>**Low temperature steam and formaldehyde sterilization**<br>**Sterilization with hydrogen Peroxide** | Together with appropriate knowledge of attributed IAF codes in the product category<br>Technical scope according to IAF MD 8:2023 - Table 1.5<br>Mainly relevant for MS of specialized sterilizers / contractors and/or manufacturers of medical devices and / or their legal representatives |
| SN EN ISO 13485:2016 | **DEVICES INCORPORATING / UTILIZING SPECIFIC SUBSTANCES / TECHNOLOGIES**<br><br>**Medical devices incorporating medicinal substances**<br>**Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed** | Technical scope according to IAF MD 8:2023 - Table 1.6<br>Mainly relevant for MS of manu facturers of medical devices and/or their legal representatives<br><br>Mainly relevant for MS of manufacturers of medical devices and/or their legal representatives |
| SN EN ISO 13485:2016 | **PARTS AND SERVICES**<br><br><br><br><br><br><br>**Raw materials**<br>Raw metals, plastic, wood, ceramic<br>**Components**<br>Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic | Technical scope according to IAF MD 8: 2023 – Table 1.7<br>Mainly relevant for MS of manu facturers and/or sub-assemblers and/or distributors of medical devices<br>Together with appropriate knowledge of the relevant IAF Codes in the product category |

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|---|---|---|
| | **Subassemblies**<br>Electronic and mechanical subassemblies, made to drawings and/or work instructions area<br>**Distribution services**<br>Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices<br>**Maintenance services**<br>Electrical or mechanical repair services<br>Facility cleaning and maintenance services<br>Uniform cleaning and testing of ESD smocks<br>**Transportation services**<br>Trucking, shipping<br>Air transportation service in general<br>**Other services**<br>Consulting services related to medical devices<br>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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