



## 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: 24.03.2020 to 23.03.2025

Scope of accreditation see: [www.sas.admin.ch](http://www.sas.admin.ch)  
(Accredited bodies)

### Scope of accreditation as of 24.03.2020

#### 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
	Rubber and plastic products	14
	Concrete, cement, lime, plaster etc.	16



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Standards	Approved technical scopes	Remarks
ISO 45001:2018 BS OHSAS 18001:2007	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
	Occupational health and safety management systems	
		IAF Code
	Food products, beverages and tobacco	3
	Publishing companies	8
	Printing companies	9
	Chemicals, chemical products and fibres	12
	Pharmaceuticals	13



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Standards	Approved technical scopes	Remarks
	Rubber and plastic products	14
	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
	Water supply	27
	Construction	28
	Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods	29
	Hotels and restaurants	30
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	Other services	35
	Education	37
	Health and social work	38
	Other social services	39
Management system certification (all international standards of the series ISO 13485)		As a general rule, the following applies to certification in the field of medical devices: - Only certification according to the norms ISO 13485 without requirements to MDO, 93/42/EEC and (EU) 2017/745. - The norm SN EN ISO 13485: 2012 is valid until at least 27.02.2019.



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Standards	Approved technical scopes	Remarks
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 0000 Non Active Medical Devices</b>	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 0100 General non-active, non-implantable medical devices</b> <ul style="list-style-type: none"> <li>- MD 0101 Non-active devices for anaesthesia emergency and intensive care</li> <li>- MD 0102 Non-active devices for injection, infusion, transfusion and dialysis</li> <li>- MD 0103 Non-active orthopaedic and rehabilitation devices</li> <li>- MD 0104 Non-active medical devices with measuring function, reusable instruments</li> <li>- MD 0105 Non-active ophthalmologic devices</li> <li>- MD 0106 Non-active instruments</li> <li>- MD 0107 Contraceptive medical devices, single-use medical devices</li> <li>- MD 0108 Non-active medical devices for disinfecting, cleaning, rinsing</li> <li>- MD 0110 Non-active medical devices for ingestion</li> </ul>	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 0200 Non-active implants</b> <ul style="list-style-type: none"> <li>- MD 0202 Non-active orthopaedic implants</li> <li>- MD 0203 Non-active functional implants</li> </ul>	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 0300 Devices for wound care</b> <ul style="list-style-type: none"> <li>- MD 0301 Bandages and wound dressings</li> <li>- MD 0302 Suture material and clamps</li> <li>- MD 0303 Other medical devices for wound care</li> </ul>	



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Standards	Approved technical scopes	Remarks
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 0400 Non-active dental devices and accessoires</b>  - MD 0401 Non-active dental equipment and instruments  - MD 0402 Dental materials  - MD 0403 Dental implants	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 1000 Active Medical Devices</b>	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 1100 General active medical devices</b>  - MD 1106 Active dental devices  - MD 1109 Active devices for patient positioning and transport	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 1200 Devices for imaging</b>  - MD 1202 Imaging devices utilizing non-ionizing radiation	
SN EN ISO 13485:2012 SN EN ISO 13485:2016	<b>MD 1300 Monitoring devices</b>  - MD 1301 Monitoring devices of non-vital physiological parameters	
<b>SN EN ISO 13485:2012</b> <b>SN EN ISO 13485:2016</b>	<b>MDS 7000 Specifics of Medical Devices</b>  - MDS 7001 Medical devices incorporating medicinal substances, according to Directive 2001/83/EC  - MDS 7004 Medical devices referencing the Directive 2006/42/EC on machinery  - -MDS 7006 Medical devices in sterile condition  - -MDS 7009 Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed	
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 (Replaces EN 729-2)



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ISO 22000:2018 ISO 22000:2005	Food safety management systems Cluster / categories 2 - 6	The certification body 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 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
	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
ISO 50001:2011	Energy Management Systems - Industry – light to medium - Industry – heavy - Mining - Energy supply - Buildings - Building complexes - Transport - Agriculture	The certification body fulfils the requirements of the standard ISO 50003:2014  Already granted certificates according to the standard ISO 50001:2011 keep their validity until 31.08.2021, at the latest.

Abbreviation	Signification
IAF Code	IAF ID1:2014
(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
MDO	Swiss Medical Device Ordinance, SR 812.213
93/42/EEC	Council directive 93/42/EEC of 14 June 1993 concerning medical devices

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