



**Accreditation number**  
Accreditation standard

**SCESm 047**  
ISO/IEC 17021

## SCES Directory

page 1 of 5

### Certification body for management systems

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<http://www.quality-service.ch>  
24.03.1998  
24.03.2008  
[www.sas.ch](http://www.sas.ch) (accredited bodies)

### Scope of accreditation in February 2011

Standards	Approved technical scopes	Remarks
ISO 9001:2008 / ISO 14001:2004	- Mining and quarrying	EA Code 2
	- Food products, beverages and tobacco	3
	- 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
	- 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	



Accreditation number  
Accreditation standard

SCESm 047  
ISO/IEC 17021

## SCES Directory

page 2 of 5

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ISO 9001:2008 / ISO 14001:2004	<ul style="list-style-type: none"> <li>- Financial intrmediation, real estate, renting</li> <li>- Information technology without software development</li> <li>- Engineering services</li> <li>- Other services</li> <li>- Public administratioin</li> <li>- Education</li> <li>- Health and social work</li> <li>- Other social services</li> </ul>	<p>32</p> <p>33</p> <p>34</p> <p>35</p> <p>36</p> <p>37</p> <p>38</p> <p>39</p>
ISO 13485:2003	<p><b>MD 0000 Non Active Medical Devices</b></p> <p><i>MD 0100 General non-active, non-implantable medical devices</i></p> <ul style="list-style-type: none"> <li>- MD0101 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</li> <li>- MD 0105 Non-active ophthalmologic devices</li> <li>- MD 0106 Non-active instruments</li> <li>- MD 0107 Contraceptive medical devices</li> <li>- MD 0108 Non-active medical devices for disinfecting, cleaning, rinsing</li> </ul> <p><i>MD 0200 Non-active implants</i></p> <ul style="list-style-type: none"> <li>- MD 0202 Non-active orthopaedic implants</li> <li>- MD 0203 Non-active functional implants</li> </ul> <p><i>MD 0300 Devices for wound care</i></p> <ul style="list-style-type: none"> <li>- MD 0301 Bandages and wound dressings</li> </ul>	<p><b><u>MDO Annex 3</u></b></p> <p>93/42/EEC</p> <p>Full quality assurance system according to annex II</p> <p>Production quality assurance according to annex V</p> <p>Product quality assurance according to annex VI</p> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>- MD 0101, 0102, 0103, 0105, 0108: single-use medical devices and reusable instruments</li> <li>- MD 0104: reusable instruments</li> <li>- MD 0107: single-use medical devices</li> </ul>



Accreditation number  
Accreditation standard

SCESm 047  
ISO/IEC 17021

## SCES Directory

page 3 of 5

Standards	Approved technical scopes	Remarks
ISO 13485:2003	<ul style="list-style-type: none"> <li>- MD 0302 Suture material and clamps</li> <li>- MD 0303 Other medical devices for wound care</li> </ul> <p><i>MD 0400 Non-active dental devices and accessories</i></p> <ul style="list-style-type: none"> <li>- MD 0401 Non-active dental equipment and instruments</li> <li>- MD 0402 Dental materials</li> <li>- MD 0403 Dental implants</li> </ul> <p><b>MD 1000 Active Medical Devices</b></p> <p><i>MD 1100 General active medical devices</i></p> <ul style="list-style-type: none"> <li>- MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia</li> <li>- MD 1105 Active ophthalmologic devices</li> <li>- MD 1106 Active dental devices</li> <li>- MD 1107 Active devices for disinfection and sterilisation</li> <li>- MD 1108 Active rehabilitation devices and active prostheses</li> <li>- MD 1109 Active devices for patient positioning and transport</li> </ul> <p><i>MD 1200 Devices for imaging</i></p> <ul style="list-style-type: none"> <li>- MD 1201 Imaging devices utilising ionizing radiation</li> <li>- MD 1202 Imaging devices utilising non-ionizing radiation</li> </ul> <p><i>MD 1300 Monitoring devices</i></p> <ul style="list-style-type: none"> <li>- MD 1301 Monitoring devices of non-vital physiological parameters</li> </ul> <p><i>MD 1400 Devices for radiation therapy and thermo therapy</i></p> <ul style="list-style-type: none"> <li>- MD 1401 Devices utilising ionizing radiation</li> </ul>	<p><b><u>MDO Annex 3</u></b> 93/42/EEC</p> <p>Full quality assurance system according to annex II Production quality assurance according to annex V Product quality assurance according to annex VI</p> <p><b>Limitations:</b> MD 1102, 1105, 1107, 1301, 1401, 1402, 1403: Measuring equipment as accessories for medical devices</p>



Accreditation number  
Accreditation standard

SCESm 047  
ISO/IEC 17021

## SCES Directory

page 4 of 5

Standards	Approved technical scopes	Remarks
ISO 13485:2003	<ul style="list-style-type: none"> <li>- MD 1402 Devices utilising non-ionizing radiation</li> <li>- MD 1403 Devices for hyperthermia / hypothermia</li> </ul> <p><b>MDS 7000 Specifics of Medical Devices</b></p> <ul style="list-style-type: none"> <li>- MDS 7001 Medical devices incorporating medicinal substances, according to Directive 2001/83/EC</li> <li>- MDS 7004 Medical devices referencing the Directive 2006/42/EC on machinery</li> <li>- MDS 7005 Medical devices referencing the Directive 89/686/EEC on personal protective equipment (PPE)</li> <li>- MDS 7006 Medical devices in sterile condition</li> <li>- MDS 7009 Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed</li> </ul>	
EN 729-2 / ISO 3834-2	Quality requirements for welding Comprehensive quality requirements	
OFAS-AI 2000	Home for disabled	Supplement 4 to the circular letter concerning the granting of subsidies to residential establishments and day care centers for invalids
BS OHSAS 18001	Occupational health and safety management systems	
ISO 22000:2005	Cluster 2 - 6 2. Food and Feed Processing (C – F)	ISO/TS 22003 sectors C Processing (Animal perishable product) D Processing (Vegetal perishable product) E Processing (Stable product) F Feed production



**Accreditation number**  
Accreditation standard

**SCESm 047**  
ISO/IEC 17021

## SCES Directory

page 5 of 5

Standards	Approved technical scopes	Remarks
	3. Distribution, Transport and Storage (H + J)	H Distribution J Transport and storage
	4. Catering (G)	G Catering
	5. (Bio) Chemicals (L)	L (Bio)chemical manufacturing
	6. Auxiliary Industries (I – M)	I Services K Equipment manufacturing M Packaging material manufacturing

### Abbreviations:

MDO	Swiss Medical Device Ordinance of the 17. October 2001 (state of 28 December 2001), SR 812.213 Annex 3: Procedures of conformity assessment
Ref. 93/42/EEC	Council directive 93/42/EEC of 14 June 1993 concerning medical devices
EA Code	EA-7/01, first edition, February 1998
FSIO	Swiss Federal Social Insurance Office
DI	Disability Insurance
ISO 13485	edition of: 2003-07 Quality systems – Medical devices – Requirements for regulatory purposes