



**Accreditation number**  
Accreditation standard

**SCESm 047**  
ISO/IEC 17021

## SCES Directory

page 1 of 5

### Certification body for management systems

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

### Branches and district offices:

- 1) QS Zürich AG  
Branch Basel  
Hangstrasse 47  
4144 Arlesheim
- 2) QS Italy S.r.l.  
C.so Merdionale, 39  
I-80143 Napoly  
Italy  
Phone: 0039 081 563 05 23
- 3) QS Zurich KOREA  
Industry Standard  
Certification Korea Co. Ltd.  
RM 705, City 2000 Officetel  
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SCESm 047  
ISO/IEC 17021

## SCES Directory

page 2 of 5

### Scope of accreditation in July 2008

Standards	Approved technical scopes	Remarks / Validity for the branches and district offices
ISO 9001:2000 / ISO 14001:2004	<ul style="list-style-type: none"> <li>- Mining and quarrying</li> <li>- Food products, beverages and tobacco</li> <li>- Publishing companies</li> <li>- Printing companies</li> <li>- Chemicals, chemical products and fibres</li> <li>- Pharmaceuticals</li> <li>- Rubber and plastic products</li> <li>- Concrete, cement, lime, plaster etc.</li> <li>- Basic metals and fabricated metal products</li> <li>- Machinery and equipment</li> <li>- Electrical and optical equipment</li> <li>- Other transport equipment</li> <li>- Manufacturing not elsewhere classified</li> <li>- Recycling</li> <li>- Water supply</li> <li>- Construction</li> <li>- Wholesale and retail trade; repair of motor vehicles, motorcycles and personal and household goods</li> <li>- Hotels and restaurants</li> <li>- Transport, storage and communication</li> <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>EA Code                      1, 2, 3</p> <p>2</p> <p>3</p> <p>8</p> <p>9</p> <p>12</p> <p>13</p> <p>14</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>22</p> <p>23</p> <p>24</p> <p>27</p> <p>28</p> <p>29</p> <p>30</p> <p>31</p> <p>32</p> <p>33</p> <p>34</p> <p>35</p> <p>36</p> <p>37</p> <p>38</p> <p>39</p>



Accreditation number  
Accreditation standard

SCESm 047  
ISO/IEC 17021

## SCES Directory

page 3 of 5

Standards	Approved technical scopes	Remarks / Validity for the branches and district offices
ISO 13485:2003	<p><b>Medical devices - Quality management systems - Requirements for regulatory purposes</b></p> <p><b>Non-active medical devices</b></p> <ul style="list-style-type: none"> <li>- skeleton implants</li> <li>- functional implants</li> <li>- single use medical products</li> <li>- reusable medical instruments</li> <li>- surgical instruments</li> <li>- wound dressings and bandages</li> <li>- sutures and surgical clips</li> <li>- instruments and equipment for dentistry</li> <li>- dental materials</li> <li>- dental implants</li> </ul> <p><b>Active medical devices</b></p> <ul style="list-style-type: none"> <li>- patient storage and transport equipment</li> <li>- dental equipment</li> <li>- diagnostic devices without ionising radiation</li> <li>- measuring equipment as accessories to medical devices</li> <li>- prosthesis and equipment for rehabilitation</li> </ul>	<p style="text-align: right;">1</p> <p>MDO, Annex 3</p> <p>ref. 93/42/EEC, annex II, V, VI:</p> <ul style="list-style-type: none"> <li>- Full quality assurance system</li> <li>- Production quality assurance</li> <li>- Product quality assurance</li> </ul> <p>MDO, Annex 3</p> <p>ref. 93/42/EEC, annex II, V, VI:</p> <ul style="list-style-type: none"> <li>- Full quality assurance system</li> <li>- Production quality assurance</li> <li>- Product quality assurance</li> </ul>
EN 729-2 / ISO 3834-2	Quality requirements for welding Comprehensive quality requirements	1
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
QuaTheDA 2000	Treatment and rehabilitation of addicted persons	1



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ISO/IEC 17021

## SCES Directory

page 4 of 5

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OHSAS 18001	Occupational health and safety management systems	1
ISO 22000	Managementsystems for the food safety  A Farming 1 (Animals) B Farming 2 (Plants) C Processing 1 (Perishable animal products) including all activities after farming, e.g. slaughtering D Processing 2 (Persishable vegetal products) E Processing 3 (Products with long shelf life at ambient temperature) F Feed production G Catering H Distribution I Services J Transport and storage K Equipment manufacturing L (Bio)chemical manufacturing M Packaging material manufacturing	1

### Abbreviations:

MDO	Swiss Medical Device Ordinance of the 17. October 2001 (state of 28 December 2001), SR 812.213
Ref. 93/42/EEC	Annex 3: Procedures of conformity assessment 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
QuaTheDA 2000	Quality Therapy Drugs Alcohol, a quality improvement project of the swiss Federal Office of Public Health for residential drug and alcohol treatment. Ref. <a href="http://www.infoset.ch/inst/quatheda/f/index.htm">http://www.infoset.ch/inst/quatheda/f/index.htm</a>