



**Accreditation number** SCESm 001  
**Accreditation standard** ISO/IEC 17021

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### Certification body for management systems

|   |  |  |
|---|--|--|
| Swiss Association for Quality<br>and Management Systems<br>(SQS)<br>Bernstrasse 103<br>CH-3052 Zollikofen | Head:  | René Wasmer  |
|   | Responsible for MS:  | René Wasmer  |
|   | General management systems:                                    | René Wasmer  |
|   | Technical management systems:                                  | Roland Glauser   |
|   | Telephone:   | +41 31 910 35 35                                       |
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|   | Internet:  | <a href="http://www.sqs.ch">http://www.sqs.ch</a>      |
|   | First accreditation (d,m,y):                                   | 21.07.1992   |
|   | Last accreditation (d,m,y):                                    | 12.08.2007   |
| Updated version:  | <a href="http://www.sas.ch">www.sas.ch</a> (accredited bodies) |  |

### Scope of accreditation in January 2012

| Standards     | Approved technical scopes                          | Remarks      |
|---------------|--|--------------|
| ISO 9001:2008 | Agriculture, fishing                               | EA Code<br>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            |
|               | 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           |



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| Standards                                  | Approved technical scopes  | Remarks  |
|--|--|--|
| ISO 9001:2008                              | 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   |
|  | Information technology   | 33   |
|  | Engineering services   | 34   |
|  | Other services   | 35   |
|  | Public administration  | 36   |
|  | Education  | 37   |
|  | Health and social work   | 38   |
| Other social services                      | 39   |  |
| ISO 14001:2004                             |  | EA 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  |
|  | Manufacture of coke and refined petroleum products   | 10   |
| Manufacture and processing of nuclear fuel | 11   |  |



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|--|--|---------|---|
| ISO 14001:2004                                 | 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   |         |   |
| Information technology                         | 33   |         |   |
| Engineering services                           | 34   |         |   |
| Other services                                 | 35   |         |   |
| Public administration                          | 36   |         |   |
| Education                                      | 37   |         |   |
| Health and social work                         | 38   |         |   |
| Other social services                          | 39   |         |   |
| AQAP 2110: 2003<br>NATO-QS-Requirements        | Same scope as ISO 9001:2000  |         |   |
| BS OHSAS 18001:2007                            | Occupational health and safety management systems  |         |   |



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| Standards                | Approved technical scopes                                   | Remarks   |
|--------------------------|---|---|
| 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    |
| eduQua: 2004             | Education   | Swiss quality certificate for adult training institutes   |
| SVOAM-2005<br>SVOAM-2010 | Measures of the employment market                           | Swiss association of the organisers of measures of the employment market. SVOAM-2005 certificates are only valuable until the 31.12.2014.   |
| QuaThéDA 2006 (modular)  | Treatment and rehabilitation of addicted persons            |   |
| ISO 22000:2005           | Food safety management systems – Cluster / categories 2 - 6 | ISO/TS 22003 sectors  |
|                          | 2. Food and Feed Processing (C – F)                         | C Processing (Animal perishable product)<br>D Processing (Vegetal perishable product)<br>E Processing (Stable product)<br>F Feed production |
|                          | 3. Distribution, Transport and Storage (H + J)              | H Distribution<br>J Transport and storage   |
|                          | 4. Catering (G)   | G Catering  |
|                          | 5. (Bio) Chemicals (L)                                      | L (Bio)chemical manufacturing   |
|                          | 6. Auxiliary Industries (I – M)                             | I Services<br>K Equipment manufacturing<br>M Packaging material manufacturing   |



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| ISO 22000<br>PAS 220 or ISO 22002-1<br>Inclusive additional FSSC 22000 requirements                                 | Food Safety System Certification 22000 (FSSC 22000) for the categories:<br><br>C Processing 1<br>(Perishable animal products)<br><br>D Processing 2<br>(Perishable vegetal products)<br><br>E Processing 3<br>(Products with long shelf life at ambient temperature)<br><br>L<br>(Bio)chemical manufacturing (food ingredients i.e. vitamins, additives and bio-cultures, but excluding technical and technological aids) | Accreditation provided in accordance with ISO/TS 22003 |
| FAMI-QS:<br>- European Code of Practice for Feed Additives and Premixture Operators<br>- Guidance on Implementation | Production of feed additives and premixes for the feed industry   | None   |
| DIN EN 15593:2008   | Packaging - Management of hygiene in the production of packaging for foodstuffs. Requirements.  |  |
| ISO/IEC 20000-1:2011  | IT Service Management   |  |
| ISO/IEC 27001:2005  | Information Security Management Systems ISMS  |  |



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| <p>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)</p> | <p>Data Protection Management Systems (DPMS) in accordance with Article 4 ODPC: Certification of Organization and Procedures</p>   | <p>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)</p>                                     |
| <p>ISO 13485:2003</p>   | <p><b>MD 0000 Non Active Medical Devices</b><br/><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 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><b><u>MDO Annex 3</u></b><br/>93/42/EEC</p> <p>Full quality assurance system according to annex II<br/>Production quality assurance according to annex V<br/>Product quality assurance according to annex VI</p> |



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| <p>ISO 13485:2003</p> | <ul style="list-style-type: none"> <li>- MD 0204 Non-active soft tissue 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> <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 1101 Devices for extra-corporal circulation, infusion and haemopheresis</li> <li>- MD 1102 Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia</li> <li>- MD 1103 Devices for stimulation or inhibition</li> <li>- MD 1104 Active surgical devices</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> </ul> | <p><b><u>MDO Annex 3</u></b><br/>93/42/EEC</p> <p>Full quality assurance system according to annex II<br/>Production quality assurance according to annex V<br/>Product quality assurance according to annex VI</p> <p><b>Limitations:</b></p> <ul style="list-style-type: none"> <li>- MD 1101</li> <li>- MD 1102</li> </ul> |



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| ISO 13485:2003 | <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 1400 Devices for radiation therapy and thermo therapy</i></p> <ul style="list-style-type: none"> <li>- MD 1404 Devices for (extracorporeal) shock-wave therapy (lithotripsy)</li> </ul> <p><b>MDS 7000 Specifics of Medical Devices</b></p> <ul style="list-style-type: none"> <li>- MDS 7004 Medical devices referencing the Directive 2006/42/EC on machinery</li> <li>- MDS 7006 Medical devices in sterile condition</li> </ul> <p><b>IVD 0000 In vitro diagnostic medical devices</b></p> <p>IVD 0300 list B: Reagents, reagent products and devices for self-diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating</p> <ul style="list-style-type: none"> <li>- IVD 0309 Device for self-diagnosis: device for the measurement of blood sugar</li> </ul> | <p><b><u>MDO Annex 3</u></b><br/>98/79/EC<br/>Full quality assurance system according to annex IV<br/>Production quality assurance according to annex VII</p> |
| ISO 15378:2006 | <p>Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2000, with reference to Good Manufacturing Practice (GMP) (ISO 15378 : 2006)</p>  | <p>Certification combined with ISO 9001</p>   |



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| Good Medical Practice <sup>®</sup>   | <ul style="list-style-type: none"> <li>- general practitioner's practices</li> <li>- Health Maintenance Organization (HMO) – group medicine</li> </ul>  | Certification of managementsystem for medical practices – quality label for medical practices  |
| RQS: 2004  | Reference document for Hospital Pharmacies developed by GSASA and APEQ  |  |
| EN 9100:2003<br>EN 9100:2009   | Management Systems for Aerospace industry   |  |
| EN 9120:2005<br>EN 9120:2010   | Management Systems for Aerospace industry / requirements for stockist distributors  |  |
| ISO 3834-2:2005  | Quality requirements for welding<br>Comprehensive quality requirements  | Combined with a certification based on ISO 9001  |
| SR 819.121 Verordnung über die Sicherheit von Druckgeräten<br>(Druckgeräteverordnung vom 20. November 2002<br>Pressure Equipment Directive 97/23/EC) | Quality assurance production<br>Quality assurance products<br>Quality assurance production<br>Quality assurance products<br>Complete quality assurance without draft examination and surveillance of the final verification | Annex III – module D1<br>Annex III – module E1<br>Annex III – module D<br>Annex III – module E<br>Annex III – module H<br><br><i>Indication</i><br>The modules A1, B, B1, C1 F, G and module H1 without quality assurance are covered by SCESp 049 |
| Ordinance on the safety of lifts   | Lifts   | SR 819.13, Annex 8, Annex 9, Full quality assurance system (modul H), Annex 10<br>Excluded are draft examinations according to the Ordinance of the safety of lifts, Annex 9, point 3.3  |



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| MoU ECM in combination with the document SAS 524 | Planning, Organisation and direction of the maintenance of freight wagons | The validity of this management system is limited until the implementation of the European basis (scheduled 1 <sup>st</sup> March 2012) |

### Abbreviations

|                |   |
|----------------|---|
| EA Code        | see SAS document 509 pt. 7.2 and annex 1  |
| eduQua         | Certification body for quality management system in adult training institutes.<br>Ref. <a href="http://www.eduqua.ch">www.eduqua.ch</a>   |
| FAMI-QS        | FAMI-QS European Feed Additives and Premixtures Quality System, Brussels,<br>Actual version of the standard document<br><a href="http://www.fami-qs.org/">http://www.fami-qs.org/</a>   |
| MDO            | Swiss Medical Device Ordinance of the 17 October 2001,<br>(state of 28 December 2001), SR 812.213   |
| MoU / ECM      | Memorandum of Understanding / Entity in Charge of Maintenance   |
| ODPC           | Ordinance on Date Protection Certification  |
| QuaTheDA       | Quality Therapy Drugs Alcohol, a quality improvement project of the Swiss<br>Federal Office of Public Health for institutes dealing with drug and alcohol<br>problems. Ref. <a href="http://www.infoset.ch/inst/quatheda/d/index.htm/">http://www.infoset.ch/inst/quatheda/d/index.htm/</a> |
| ref. 93/42/EEC | Council Directive 93/42/EEC of the 14 June 1993 on medical devices  |
| ref. 98/79/EC  | Council Directive 98/79/EC of the European Parliament and of 27 October 1998<br>on in vitro diagnostic medical devices  |