



## MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

### Scope of Accreditation

**Accredited Legal Entity:** DQS Medizinprodukte GmbH

Contact Name: Marc Goedecke

Address: August-Schanz- Straße 21  
60433 Frankfurt am Main  
Germany

Telephone: 49 69 95427-8107

Fax: 49 69 95427-6273

Website: [www.dqsglobal.com](http://www.dqsglobal.com)

Email: [marc.goedecke@dqs.de](mailto:marc.goedecke@dqs.de)

**Operating out of:** Konrad-Adenauer-Allee 8-10  
61118 Bad Vilbel  
Germany

<b>SCC File Number:</b>	08047
<b>Accreditation Standards:</b>	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD4, MD5, MD9 (where applicable)
<b>Initial Accreditation:</b>	2011-01-24
<b>Most Recent Accreditation:</b>	2023-03-02
<b>Accreditation Valid to:</b>	2027-01-24

### I: Medical Device Management Systems Program

<b>Base program:</b>	Medical Device Management Systems (MDMS)
<b>Additional accreditation standards</b>	IAF MD 9:2022

<b>Certification standards:</b>	ISO 13485:2016	
<b>Locations:</b>	A	
<b>Certification Body's main technical areas:</b>	Non-active Medical Devices	<ul style="list-style-type: none"> <li>• General non-active, non-implantable medical devices</li> <li>• Non-active implants</li> <li>• Devices for wound care</li> <li>• Non-active dental devices and accessories</li> </ul>
	Active Medical Devices (Non-Implantable)	<ul style="list-style-type: none"> <li>• General active medical devices</li> <li>• Devices for imaging</li> <li>• Monitoring devices</li> <li>• Devices for radiation therapy and thermo therapy</li> </ul>
	In Vitro Diagnostic Medical Devices (IVD)	<ul style="list-style-type: none"> <li>• Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> <li>– Clinical Chemistry</li> <li>– Immunochemistry (Immunology)</li> <li>– Haematology/Haemostasis/Immuno-hematology</li> <li>– Microbiology</li> <li>– Infectious Immunology</li> <li>– Histology/Cytology</li> <li>– Genetic Testing</li> </ul> </li> <li>• In Vitro Diagnostic Instruments and software</li> </ul>
	Sterilization Method for Medical Devices	<ul style="list-style-type: none"> <li>• Ethylene oxide gas sterilization (EOG)</li> <li>• Moist heat</li> <li>• Aseptic processing</li> <li>• Radiation sterilization (e.g. gamma, x-ray, electron beam)</li> <li>• Sterilization method other than specified above</li> </ul>
	Devices incorporating/utilizing specific substances/technologies	<ul style="list-style-type: none"> <li>• Medical devices incorporating medicinal substances</li> <li>• Medical devices utilizing tissues of animal origin</li> <li>• Medical devices incorporating derivatives of human blood</li> <li>• Medical devices utilizing micromechanics</li> <li>• Medical devices utilizing nanomaterials</li> <li>• Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed</li> </ul>
	Parts and Services	<ul style="list-style-type: none"> <li>• Raw materials</li> <li>• Components</li> </ul>

		<ul style="list-style-type: none"><li>• Subassemblies</li><li>• Calibration services</li><li>• Distribution services</li><li>• Maintenance services</li><li>• Transportation services</li><li>• Other services</li></ul>
--	--	--

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to DQS Medizinprodukte GmbH. The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at [www.scc.ca](http://www.scc.ca).

---

Elias Rafoul  
Vice-President, Accreditation Services  
Publication on: 2023-03-03