



## MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

### Scope of Accreditation

**Accredited Legal Entity:** TÜV USA, Inc.  
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#### LOCATION A

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<b>SCC File Number:</b>	08043
<b>Accreditation Standards:</b>	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD5 (where applicable)
<b>Initial Accreditation Date:</b>	2008-02-12
<b>Reaccreditation Date:</b>	2016-08-17
<b>Accreditation Expiry Date:</b>	2020-02-12

#### VI: Medical Devices Quality Management Systems Program

<b>Base program:</b>	Medical Devices Quality Management Systems	
<b>Additional accreditation standards</b>	GD207; GD210; GD211; Q90R0 IAF MD9	
<b>Certification standards:</b>	ISO 13485:2003 under CMDCAS ISO 13485:2003	
<b>Locations:</b>	A	
<b>Certification Body's main technical areas: (IAF MD 8 &amp; MD 9)</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> <li>• Non-active medical devices other than specified</li> </ul>



		above
	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> Active (non-implantable) medical devices other than specified above
	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/Immunoheatology</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)Moist heat</li><li>• Aseptic processing</li><li>• Radiation sterilization (e.g. gamma, x-ray, electron beam)</li></ul>
	Devices incorporating/utilizing specific substances/technologies	<ul style="list-style-type: none"><li>• Medical devices utilizing tissues of animal origin</li><li>• Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed</li></ul>

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to TÜV USA, Inc. 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).

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