



## MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

### Scope of Accreditation

**Accredited Legal Entity:** Laboratoire National de métrologie et d'Essais (LNE)  
G- MED Certification Division Trading as LNE/G-MED

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Regulatory Affairs

#### LOCATION A

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<b>SCC File Number:</b>	08030
<b>Accreditation Standards:</b>	ISO/IEC 17021-1:2015 IAF MD1, MD2, MD5
<b>Initial Accreditation Date:</b>	2004-07-27
<b>Reaccreditation Date:</b>	2016-03-17
<b>Accreditation Expiry Date:</b>	2020-07-27

#### Additional Critical/Key Locations:

Location	Country	Address	City
B	France	19 D rue de la Télématique 42000 Saint-Étienne France	Saint-Étienne
C	United States	3930 Knowles Ave. Suite 306 Kensington, Maryland 20895	Maryland



**I: 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-C	
<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 above</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> <li>• Active (non-implantable) medical devices other than specified above</li> </ul>
	Active Implantable Medical Devices	<ul style="list-style-type: none"> <li>• General active implantable medical devices</li> <li>• implantable medical devices other than specified above</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/Immunoematology</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> <li>• IVD medical devices other than specified above</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 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><li>• Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above</li></ul>
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This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to Laboratoire National de métrologie et d'Essais (LNE) G- MED Certification Division Trading as LNE/G-MED 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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Vice President, Accreditation Services  
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