



## MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

### Scope of Accreditation

**Accredited Legal Entity:** Intertek Testing Services NA Inc.  
trading as Intertek and Intertek SAI Global

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#### LOCATION A

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|-----------------------------------|---|
| <b>SCC File Number:</b>           | 08006   |
| <b>Accreditation Standards:</b>   | ISO/IEC 17021-1:2015<br>IAF MD 1:2023<br>MD 2:2023<br>MD 4:2023 |
| <b>Initial Accreditation:</b>     | 1993-02-02  |
| <b>Most Recent Accreditation:</b> | 2024-03-28  |
| <b>Accreditation Valid to:</b>    | 2027-02-02  |

#### Additional Fixed Office Locations (FOL):

See the address of the above legal entity. No other location is included in the accreditation.

#### I: Medical Device Management Systems Program

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| <b>Base program:</b>                      | Medical Device Management Systems (MDMS) |
| <b>Additional accreditation standards</b> | IAF MD 9:2023                            |

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| <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 thermos 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/Immunohematology</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>      |
|   | Parts and Services  | <ul style="list-style-type: none"> <li>• Components</li> </ul>  |

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|--|--|--|
|  |  | <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> |
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This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to Intertek Testing Services NA Inc. The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at [scc-ccn.ca](https://www.scc-csc.ca).

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Vice-President, Accreditation Services  
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