Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **DEKRA Certification B.V.**

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LOCATION A

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SCC File Number:	08046
Accreditation Standards:	17021-1:2015 IAF MD1, MD2, MD5, MD11
Initial Accreditation Date:	2009-04-06
Reaccreditation Date:	2017-03-31
Accreditation Expiry Date:	2021-04-06

Additional Critical/Key Locations:

Location	Country	Address	City
B	USA	*DEKRA Certification Inc.* *USA Eastern office:* *1120 Welsh Road – Suite 210* *North Wales, PA 19454* *Telephone: +1 215 997 3815* *Telefax: +1 215 997 9736* *medical.us@dekra.com*	North Wales
C	USA	*DEKRA Certification Inc.* *USA Western office:* *1850 Gateway Blvd – Suite 925,* *Concord, CA 94520* *Telephone: +1 925 283 7559* *Telefax: +1 925 283 7553* *medical.us@dekra.com*	Concord

I: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems	
Additional accreditation standards	GD207; GD210; GD211; Q90R0 (for CMDCAS only) IAF MD9 (for non-CMDCAS)	
Certification standards:	ISO 13485:2003 under CMDCAS ISO 13485:2016 under CMDCAS ISO 13485:2003 ISO 13485:2016	
Locations:	A, B, C	
Certification Body's main technical areas: (IAF MD 8 & MD 9)	Non-active Medical Devices	• General non-active, non-implantable medical devices • Non-active implants • Devices for wound care • Non-active dental devices and accessories • Non-active medical devices other than specified above
	Active Medical Devices (Non-Implantable)	• General active medical devices • Devices for imaging • Monitoring devices • Devices for radiation therapy and thermo therapy • Active (non-implantable) medical devices other than specified above
	Active Implantable Medical Devices	• General active implantable medical devices • implantable medical devices other than specified above
	In Vitro Diagnostic Medical Devices (IVD)	• Reagents and reagent products, calibrators and control materials for: – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immunohematology – Microbiology – Infectious Immunology – Histology/Cytology – Genetic Testing • In Vitro Diagnostic Instruments and software • IVD medical devices other than specified above
	Sterilization Method for Medical Devices	• Ethylene oxide gas sterilization (EOG) • Moist heat • Aseptic processing • Radiation sterilization (e.g. gamma, x-ray, electron beam) • Sterilization method other than specified above

	Devices incorporating/utilizing specific substances/technologies	• Medical devices incorporating medicinal substances • Medical devices utilizing tissues of animal origin • Medical devices incorporating derivatives of human blood • Medical devices utilizing micromechanics • Medical devices utilizing nanomaterials • Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed • Medical devices incorporating or utilizing specific substances/technologies/ elements, other than specified above

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to DEKRA Certification B.V. The original version is available in the Directory of Accredited Management Systems Certification Bodies on the SCC website at www.scc.ca.

Chantal Guay, ing., P.Eng.
Vice President, Accreditation Services
Date: 2017-03-31