

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
В	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
С	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

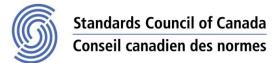




I: Medical Devices Quality Management Systems Program

Base	Medical Devices Quality Management Systems		
program:	Medical Devices Quality Management Gystems		
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 	





specific	ating/utilizing es/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

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

