Standards Council of Canada
Conseil canadien des normes

MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **TÜV USA, Inc.**

Contact Name: Ralf Thomsen
Managing Director

LOCATION A

Address: 215 Main Street, Suite 1
Salem NH 03079 USA

Telephone: +1 603 870 8023

Fax: +1 610 903 4872

Website: www.tuv-usa.com

Email: rthomsen@tuv-nord.com

SCC File Number:	08043
Accreditation Standards:	ISO/IEC 17021:2011 IAF MD1, MD2, MD5 (where applicable)
Initial Accreditation Date:	2008-02-12
Reaccreditation Date:	2016-08-17
Accreditation Expiry Date:	2020-02-12

VI: Medical Devices Quality Management Systems Program

Base program:	Medical Devices Quality Management Systems	
Additional accreditation standards	GD207; GD210; GD211; Q90R0 IAF MD9	
Certification standards:	ISO 13485:2003 under CMDCAS ISO 13485:2003	
Locations:	A	
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

Canada

	Active Medical Devices (Non-Implantable)	• General active medical devices • Devices for imaging • Monitoring devices • Devices for radiation therapy and thermo therapy
	Sterilization Method for Medical Devices	• Ethylene oxide gas sterilization (EOG) • Aseptic processing • Radiation sterilization (e.g. gamma, x-ray, electron beam)
	Devices incorporating/utilizing specific substances/technologies	• Medical devices utilizing tissues of animal origin • Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed

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.

Chantal Guay, ing., P.Eng.
Vice President, Accreditation Services
Date: 2017-02-15

Canada