



MANAGEMENT SYSTEMS ACCREDITATION PROGRAM (MSAP)

Scope of Accreditation

Accredited Legal Entity: **SGS United Kingdom Ltd.**
Contact Name: Mr. Adrian Keene
 Global Medical Device Certification Manager

LOCATION A

Address: Rossmore Business Park,
 Ellesmere Port,
 Cheshire
 CH65 3EN
 United Kingdom

Telephone: +44 1934 522 917

Fax: +44 1934 522 137

Website: www.uk.sgs.com

Email: adrian.keene@sgs.com

**Operating out of:
 (Location A)** Unit 202B, Worle Parkway
 Weston Super Mare, Somerset
 BS22 6WA United Kingdom

SCC File Number:	08042
Accreditation Standards:	ISO/IEC 17021:2011 IAF MD1, MD2, MD4, MD5, MD11
Initial Accreditation Date:	2007-08-28
Reaccreditation Date:	2015-11-26
Accreditation Expiry Date:	2019-08-28

I: 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	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • General active implantable medical devices • implantable medical devices other than specified above
	In Vitro Diagnostic Medical Devices (IVD)	<ul style="list-style-type: none"> • Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> – Clinical Chemistry – Immunochemistry (Immunology) – Haematology/Haemostasis/Immunoematology – 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	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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



Standards Council of Canada
Conseil canadien des normes

This document forms part of the Certificate of Accreditation issued by the Standards Council of Canada (SCC) to SGS United Kingdom Ltd. 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
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