



CERTIFICATE OF ACCREDITATION

UNITED ACCREDITATION FOUNDATION INC

1060 Laskin Rd, Suite: 12B/13B, Virginia Beach VA 23451, United States of America



Has Accredited

SIS Certifications Private Limited

**UNIT No. 514, 5TH FLOOR, VIPUL BUSINESS PARK SITUATED AT SECTOR-48,
SOHNA ROAD, GURGAON, HARYANA, 122001, INDIA**

IN THE FIELD OF MANAGEMENT SYSTEMS CERTIFICATIONS

Details of Scope of Accreditation are as per the Accreditation Schedule issued with this Certificate.

ISSUE DATE: 04/04/2025



ACCREDITATION VALID FROM
08/28/2023 for MDQMS

ACCREDITATION EXPIRY
08/27/2027 for MDQMS

(DIRECTOR)

UNITED ACCREDITATION FOUNDATION INC (UAF) is a signatory of the Multilateral Recognition arrangement with International Accreditation Forum (IAF) and a signatory of the Mutual Recognition Arrangement with Asia Pacific Accreditation Cooperation (APAC).

Visit www.uafaccreditation.org for current accreditation information.



Schedule of Accreditation

Issue No: 06 Issue date: Apr 04, 2025

Name of CAB: SIS Certifications Private Limited

Key Location (s): Unit No. 514, 5th Floor, Vipul Business Park Situated at Sector-48, Sohna Road, Gurgaon, Gurgaon, Haryana, 122001, India.

Registered Office Address: House No. 1539, Sector-4, Gurgaon, Gurgaon, Haryana, 122002, India.

Countries where UAF accredited certificates can be Issued (Subject to Compliance with UAF Policy For CAB Operations in Sanctioned Countries): Algeria, Australia, Azerbaijan, Bahrain, Bangladesh, Brazil, Canada, Denmark, Egypt (subject to approval of local authorities), Ethiopia, Georgia, Germany, Ghana, Greece, India, Indonesia, Iraq, Italy, Japan, Jordan, Kenya, Kingdom of Saudi Arabia, Malaysia, Mauritius, Mexico, Morocco, Myanmar, New Zealand, Nigeria, Oman, Peru, Philippines, Qatar, Romania, Serbia, Singapore, South Africa, Spain, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, United States, Uzbekistan, Vietnam (subject to approval of local authorities).

Accredited to ISO/IEC 17021-1	Accreditation Number	Accreditation Valid Date	Accreditation Valid Up to*
Medical Devices Quality Management System	52308700617	08/28/2023	08/27/2027

*Subject to the terms and conditions that are set out in Accreditation Agreement signed by **SIS** are met and Annual Surveillances, Witnesses as per **SIS** Surveillance Program and other obligations are satisfactorily completed.

ACCREDITATION STANDARDS

ISO/IEC 17021-1: 2015 – Conformity assessment – Requirements for bodies providing audit and certification of management systems.

UAF-CAB-MDQMS: Accreditation requirements for Certification of Medical Device Quality Management System

UAF-GEN-CAB - 01: General Accreditation Requirements.

UAF-GEN-CAB - 02: Conditions for the Use of UAF Accreditation Symbol. IAF MD1:2023 – Certification of Multiple Sites based on Sampling.

IAF MD 2:2023 IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems

IAF MD 4:2023 IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes

IAF MD 9:2023 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)

IAF MD23:2023 Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies

MANAGEMENT SYSTEMS CERTIFICATION STANDARDS

ISO 13485:2016 -Medical Devices - Quality management systems-Requirements for regulatory purposes.

SCOPE OF ACCREDITATION

Medical Devices Scheme (MDQMS)

ISO 13485:2016-Medical Devices Technical Areas as detailed in Annex A of IAF MD 9:2023

Main Technical Areas	Accreditation Number
Non-active Medical Devices	General non-active, non-implantable medical devices
	Non-active implants
	Devices for wound care
	Non-active dental devices and accessories

In Vitro Diagnostic Medical Devices (IVD)	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry, Immunochemistry (Immunology) Haematology/Haemostasis/Immunoematology, Microbiology, Infectious Immunology, Histology/Cytology, Genetic Testing
	In Vitro Diagnostic Instruments and software
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilization (e.g. gamma, x-ray, electron beam)
	Low temperature steam and formaldehyde sterilization
	Thermic sterilization with dry heat
	Sterilization with hydrogen peroxide.
Parts or Services	Raw materials (Raw metals, plastic, wood, ceramic)
	Components (Electrical components, fasteners, shaped raw materials, machined raw materials and molded plastic)
	Subassemblies (Electronic subassemblies mechanical subassemblies, made to drawings and/or work instructions)
	Calibration services (Verification/confirmation services for measuring instruments, tools or test fixtures)
	Distribution services (Distributors providing storage and delivery of medical devices, not acting as a 'legal manufacturer' for medical devices)
	Maintenance services (Electrical or mechanical repair services, facility cleaning and maintenance services, uniform cleaning and testing of ESD smocks.)
	Transportation services (Trucking, shipping, air transportation service in general)
	Other services (Consulting services related to medical devices, packaging services, etc.)



Director

April 04, 2025