



CERTIFICATE OF ACCREDITATION

UNITED ACCREDITATION FOUNDATION INC

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



Has Accredited

KIHT CERTIFICATION SERVICES

**KALAM CONVENTION CENTRE, AMTZ CAMPUS, PRAGATI MAIDAN, VM STEEL PROJECT SO, VISAKHAPATNAM,
ANDHRA PRADESH-530031, 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: 11/15/2024



(DIRECTOR)

ACCREDITATION VALID FROM

04/02/2024 for MDQMS

ACCREDITATION EXPIRY

04/01/2028 for MDQMS

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: 03 Issue date: Nov-15-2024

Name of CAB: KIHT Certification Services

Key Location (s): Kalam Convention Centre, AMTZ Campus, Pragati Maidan, VM Steel Project SO, Visakhapatnam, Andhra Pradesh-530031, India

Countries where UAF accredited certificates can be Issued (Subject to Compliance with UAF Policy For CAB Operations in Sanctioned Countries): Australia, Austria, Bangladesh, Bhutan, Egypt (subject to approval by local authorities), India, Indonesia, Israel, Japan, Nepal, Qatar, Romania, Saudi Arabia, Singapore, South Africa, South Korea, Sri Lanka, Taiwan, Thailand, Turkey, United Arab Emirates, United Kingdom, Vietnam (subject to approval by local authorities)

Accredited to ISO/IEC 17021-1	Accreditation Number	Accreditation Valid Date	Accreditation Valid Up to*
Medical Devices Quality Management System	52404900624	04/02/2024	04/01/2028
*Subject to the terms and conditions that are set out in Accreditation Agreement signed by KIHT are met and Annual Surveillances, Witnesses as per KIHT 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 MD 1:2023 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization

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)

MANAGEMENT SYSTEMS CERTIFICATION STANDARDS

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

SCOPE OF ACCREDITATION

Medical Devices Quality Management System

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

Main Technical Areas	Technical Areas
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 thermos therapy
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
Sterilization Method for Medical Devices	IVD instruments and software
	Ethylene oxide gas sterilization (EOG)
	Moist Heat
	Aseptic processing
	Radiation sterilization (e.g. gamma, xray, electron beam)
	Thermic sterilization with dry heat
	Sterilization with hydrogen peroxide
Devices incorporating/utilizing specific substances/technologies	Low temperature steam and formaldehyde sterilization
	Medical devices incorporating medicinal substances
	Medical devices utilizing tissues of animal origin
	Medical devices incorporating derivates of human blood
	Medical devices utilizing micromechanics
	Medical devices utilizing nanomaterials
Parts or services	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed.
	Raw materials
	Components
	Subassemblies
	Calibration services
	Distribution services
	Maintenance services
	Transportation services
	Other services

Issued by Director
Dated: 11/15/2024