



CERTIFICATE OF ACCREDITATION

This is to attest that

HTCERT-GFI HEALTH TECHNOLOGY CERTIFICATION LIMITED

JAKOVIDES TOWER, 81-83 GRIVAS DIGENIS AVENUE
NICOSIA, 1090, REPUBLIC OF CYPRUS

Management System Certification Body MSCB-184

has met the requirements of AC477, *IAS Accreditation Criteria for Management System Certification Bodies*, and has demonstrated compliance with the ISO/IEC 17021-1:2015 Standard, *Conformity assessment – Requirements for bodies providing audit and certification of management systems*. This organization is accredited to provide the services specified in the scope of accreditation.

Effective Date May 14, 2024

(Valid as per IAS 4-year accreditation cycle subject to periodic assessments and satisfactory closure of findings)

Accredited Since March 4, 2019



President

Visit www.iasonline.org for current accreditation information.

SCOPE OF ACCREDITATION

International Accreditation Service, Inc.

3060 Saturn Street, Suite 100, Brea, California 92821, U.S.A. | www.iasonline.org

HTCERT-GFI HEALTH TECHNOLOGY CERTIFICATION LIMITED

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NICOSIA, 1090, REPUBLIC OF CYPRUS

<https://htcert.com/>

MSCB-184

Contact Name Evi Saratsioti

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Accredited to ISO/IEC 17021-1:2015

Effective Date May 14, 2024

Discipline of Certification:	Quality Management Systems
Accredited To/Additional Level 4 Standard:	ISO/IEC 17021-3:2017
Certification Standard:	ISO 9001:2015 / EN ISO 9001:2015
Certification Scheme:	N/A
Certification Sectors	
13: Pharmaceuticals 19: Electrical and Optical Equipment 23: Manufacturing Not Elsewhere Classified	29: Wholesale and Retail Trade; Repair of Motor Vehicles, Motorcycles and Personal and Household Goods 31: Transport, Storage and Communications 33: Information Technology

Discipline of Certification:	Medical Device Quality Management Systems
Certification Standard:	ISO 13485:2016 / EN ISO 13485:2016
Certification Scheme:	N/A
Main Technical Areas/Technical Areas	
Table A.1.1 – 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
Table A.1.2 – Active (Non-Implantable) Medical Devices	General active medical devices
	Devices for imaging
	Monitoring devices
	Devices for radiation therapy and thermo therapy

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HTCert-GFI Health
TEchnology Certification
Limited



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	Active (non-implantable) medical devices other than specified above
Table A.1.4 - In Vitro Diagnostic Medical Devices	Reagents and reagent products, calibrators, and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunoematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing
	IVD Instruments and software
	IVD medical devices other than specified above
Table A.1.5 – Sterilization Methods 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
Table A1.7 – Parts and Services	Raw materials
	Components
	Subassemblies
	Calibration services
	Distribution services
	Maintenance services
	Transportation services
	Other services

Note: The above scope of accreditation is based on the statistical nomenclature for economic activities NACE rev. 2 and as recommended by the current version of IAF ID 1.

The scope of accreditation represents broad classifications granted by IAS on the basis of the management system certification processes demonstrated by the certification body (CB). Accreditation is based on the competence and ability to effectively apply the requirements of the relevant certification standards listed in the CB's scope of accreditation. IAS accreditation entails review of the CBs own management system, on-site assessment of the CB's certification processes, review of CB's access to expertise including onsite observation of the CB when conducting certification audits at client sites. Under the conditions of accreditation, the CB is obligated to use equivalent certification practices covering the specific scopes as listed for all clients and as demonstrated during the accreditation process. Accreditation does not cover certification in areas outside the scope of this accreditation certificate. Accreditation does not imply endorsement of the products or the design or performance characteristics of products certified by the CB.

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Type of entity	Company name	Address (Street City, Country)	Contact information	Countries of operation
CB Key Location	N/A	N/A	N/A	N/A
CB Location (No Key Activities)	N/A	N/A	N/A	N/A
Subcontractor Key Location	N/A	N/A	N/A	N/A
Subcontractor (No Key Activities)	N/A	N/A	N/A	N/A

The above table lists any entities performing work on behalf of the accredited MSCB (See IAF MD23:2018, and IAS/MSCB/031 for information regarding types of activities per entity). Types of entities and their descriptions are as follows (please contact IAS should further clarification be required):

CB Key Location: Entities performing and/or managing key management system certification activities, on behalf of accredited certification bodies, which are wholly or partly owned or employed by the CB.

CB Location (No Key Activities): Entities performing and/or managing processes related to management system activities, on behalf of accredited certification bodies, which are wholly or partly owned or employed by the CB (processes include; marketing, communications, outreach, etc.) This list is not all-inclusive; any activity related to the accredited CBs certification program is applicable.

Subcontractor Key Location: Entities performing and/or managing key management system certification activities, on behalf of accredited certification bodies, which are not wholly or partly owned or employed by the CB.

Subcontractor (No Key Activities): Entities performing and/or managing processes related to management system activities, on behalf of accredited certification bodies, which are not wholly or partly owned or employed by the CB (processes include; marketing, communications, outreach, etc.) This list is not all-inclusive; any activity related to the accredited CBs certification program is applicable.