**SECTION- A**

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| --- | --- | --- |
| **DETAILS** | | |
| **Type of Services:** | 🞎 Initial Accreditation | 🞎 Extension in scope |
| **Certification Body’s Name:** |  | |
| **Physical Address:** |  | |
| **Tel. No.** |  | |
| **E-mail Address:** |  | |
| **Website:** |  | |
| **Managing Director/Directors** |  | |
| **Certification Manager /Operations Manager/Responsible Contact Person** |  | |
| **Date of Establishment of Certification Body** |  | |
| **Legal Status (License/ Registration Number) of Certification Body** |  | |
| **Is the Certification Body already accredited by another IAF MLA Accreditation Body** | Yes/No  (in case of “YES” please complete ‘SECTION-B’) | |

**SECTION-B**

|  |  |
| --- | --- |
| **Information in case of existing accreditation by another IAF MLA Accreditation Body** | |
| **Name of Accreditation Body** |  |
| **Date of initial accreditation** |  |
| **Date of expiry of current accreditation** |  |
| **Number of active certificates** |  |
| **Details of any unresolved complaint/issues** |  |
| **Optional:**  **Details of successful completion of witnessing by the other Accreditation Body for the last five years. Please provide information regarding the date of witness; IAF scope; Name of client where the witness was conducted in a separate sheet** | |

**SECTION-C**

|  |  |
| --- | --- |
| **OTHER DETAILS** | |
| **Other activities of CAB** |  |
| **Relationship in a larger entity if any, addresses of all its physical location(s) and, information on activities conducted at all locations including virtual site(s)** |  |
| **Related Bodies of CAB’s top management**  **(Please include complete details of all BODs & shareholders)** |  |
| **Activities executed by the related bodies** |  |
| **Requirement for preliminary visit prior to the commencement of assessment process** | Yes/No |

**SECTION-D**

|  |  |  |
| --- | --- | --- |
| **Details of Personnel** | **Employed** | **Contracted** |
| Managerial/Administrative |  |  |
| **Technical** |  |  |
| **Auditors/Lead Auditors** |  |  |
| **Technical Experts** |  |  |

**SECTION-E**

Details of any other critical location(s)/Locations other than the main/ head office or branches where \*key activities /other activities takes place then kindly specify the names of cities & countries where critical locations or Location/ branches are situated. Please attach complete Application Form UAF: AOL: 01 for each office Critical Location and location, apart from the Head Office.

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| --- | --- | --- | --- |
| # | Critical location/Location Details | City & Country | \*Key Activities /other activities carried out at this location |
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**Note*:*** \*Key activities include: policy formulation, process and/or procedure development, proceedings of safeguarding impartiality committee/scheme committee, approval of auditors/examiners/inspectors, application & contract review, selection of auditors/examiners/inspectors, handling of contractual agreements with auditors/examiners/inspectors, monitoring of auditors/examiners/inspectors, planning of audits/examinations/inspections, review, approval and decision on the results of audits/examinations/inspections and preparation, release & control of certificates. Final decision on appeals and complaints.

Please list down the name (s) of countries where certification body intends to provide UAF accredited certifications:

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| --- | --- | --- | --- | --- | --- |
| # | Name of Country | # | Name of Country | # | Name of Country |
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SECTION-F

SCOPE OF ACCREDITATIONS (as per IAF MD 9:2022)

# 

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| --- | --- | --- |
| Main Technical Area | Technical Area | Scope Applied Yes/No |
| 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 thermo therapy |  |
| Active (non-implantable) medical devices other than specified above |  |
| Active implantable medical Devices | General active implantable medical devices |  |
| Implantable medical devices other than specified above |  |
| 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 |  |
| IVD Instruments and Software |  |
| IVD medical devices other than specified above |  |
| 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 |  |
| Sterilization method other than specified above |  |
| Devices  incorporating/utilizing  specific substances/  technologies | 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 |  |
| Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed |  |
| Medical devices incorporating or utilizing specific substances/technologies/elements, other than specified above. |  |
| Parts and 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.) |  |

**SECTION-G**

**TO BE COMPLETED BY CAB’S BELONGING TO COUNTRIES OTHER THAN UNITED STATES OF AMERICA.**

|  |  |  |
| --- | --- | --- |
| Do you know, if there is a local accreditation body | If yes, Name of Accreditation Body |  |
| Are you aware if the Local Accreditation Body is running MDQMS Accreditation program? | If yes, Reason for applying to UAF. |  |
| Are you willing to allow UAF To advise your Local Accreditation Body about your application during course of Accreditation? | Please answer Yes/No |  |
| If above is Yes, Is Assessment by Local Accreditation acceptable? | Please answer Yes/No |  |
| Is joint Assessment with Local Accreditation acceptable? | Please answer Yes/No |  |

**SECTION-H**

**TERMS & CONDITIONS:**

1. All applications shall be submitted electronically in word format to UAF along with a payment of **application fees** paid as stated in Fees table.
2. The signed, stamped and scanned copy of the last page of this application form shall also be submitted.
3. By signing the Application Form, the applicant agrees to accept the below mentioned clauses:
   1. The applicant hereby confirms that the information provided in this application form is true and correct. The applicant acknowledges that he/ she agrees to abide by the following documents/ requirements, relevant to their scope of work:
   2. Comply with the Terms and conditions and Accreditation Requirements as per UAF-GEN-CAB-01.
   3. Relevant **UAF Requirements** & **Guidance Documents** issued for relevant schemes covering general, administrative &technical areas. These **Requirements** &**Guidance Documents** are defined for each type of certification body and are available on UAF website.
   4. Relevant, and if Applicable **Mandatory and Guidance Documents** issued by International Accreditation Forum (IAF) and Asia Pacific Accreditation Cooperation (APAC). These documents are available on IAF and APAC websites.
   5. To submit a current list of names and addresses of Management system certified organizations certifications that have been issued.
   6. **We confirm that we have certified minimum one client and completed certification process from receipt of application to issuance of certification for said management system.**
   7. We declare that we nor any of our certification personnel have any relationship with any person or company included in the specially designated Nationals and Blocked Persons List (SDN) Human Readable Lists.
   8. **We understand that this application will only be accepted if our CAB has certified at least one (1) client for said Management system.**
   9. List of ISO auditors the certification body plans to use, including evidence of their competency under each of the requested scopes.
   10. To confirm that at least one internal Audit and one MRM has been conducted prior to submission of application.
   11. To cooperates with UAF which is necessary to enable UAF to verify compliance with the requirements for accreditation including provision for review of documentation (including documents that provide insight into the level of independence of the applicant from any other related activities undertaken by their organization, where applicable) and access to all areas, equipment, records and personnel for the purposes of assessment, surveillance, reassessment and resolution of complaints.
   12. To comply at all times with the accreditation criteria, requirements, and conditions for accreditation.
   13. To claim that it is accredited only in respect of services for which it has been granted accreditation and which are carried out in accordance with these conditions.
   14. To pay fees and charges as are due to UAF in accordance with UAF Accreditation Fee Structure knowing that **All fees are non-refundable**.
   15. Not to make any statement relevant to its accreditation which UAF may consider misleading or unauthorized and endeavor to ensure that no certificate or report, nor any part thereof, is used in a misleading manner as per accreditation requirements of conditions for the use of UAF accreditation symbol (UAF-GEN-CAB-02)
   16. Upon suspension, withdrawal or expiration of its accreditation (however determined) discontinue the use of all advertising that contains reference thereto and return any certificates of accreditation to UAF.
   17. In case of already accredited CAB by another Accreditation Body for the applied management system, we declare that we are not under threat of suspension/withdrawal.
   18. Inform UAF in writing of changes or pending changes in any aspect of the applicant's status or operation that affects the applicant's legal, commercial or organizational status; organization or management (e.g., managerial staff); policies or procedures, where appropriate; premises; personnel, equipment, facilities, working environment or other resources, where significant; authorized signatories; or such other matters that may affect the certification body’s capability, or scope of accredited activities, or compliance with the criteria, requirements and conditions for accreditation.
   19. To assist UAF in the investigation and resolution of complaints made by any party about the certification body’s accreditation related activities.
   20. The CAB shall accept the responsibility for the safety of UAF assessors and assessors in conducting activities related to accreditation. The certification body shall provide all relevant safety or protective clothing or equipment and disclosing to assessment team any hazards.
   21. Appeals can be made in writing against any decision related to accreditation made by UAF, within thirty calendar days of receiving the decision. Appeals will be processed in accordance with the UAF Appeals Procedure.

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| **SSS**  **Signed for and on behalf of applicant** | **Full Name:** | **Designation:** |
| **Signature of Authorized Representative:** | **Date:** |

**SECTION –I**

**FOR OFFICE USE ONLY:**

* Has the applicant CAB provided all the necessary information pertaining to accreditation requirements? –Yes /No
* Is there any evidence of fraudulent behaviour of the applicant CAB which may result in the rejection of the application? –Yes /No
* Is the applicant CAB requesting for a preliminary visit prior to the commencement of assessment process? –Yes /No.
* Are the any pending complaints/issues, in case of the CAB being accredited by another AB? –Yes /No/NA

Reviewed By: Dated: