Please use BLOCK CAPITALS

Name of Organisation	
Address of Organisation providing Testing services	**Tel: Fax: E-mail:** **Web-site:**
Name of contact	
Address of contact (if different from above)	**Tel: Fax: E-mail:**
Name and Address of Parent Organisation providing Testing Services:	
Parent Organisation: **Address:**	**Tel: Fax: E-mail:** **Web-site:**

Legal Status and Date of Establishment (please give Registration No. and name of authority who granted the registration)								
Organization Registered as:								
Private limited company		**Private partnership**		**Public limited company**		**Government body**		**Other**

If Other, please specify: **.....**

Part 1 Organisation

1.1 Name and position (Director level) of person authorising this application

Name: Title	Initials	Surname
Position		

1.2 Name and address of parent organisation (if different from laboratory address on page 1)

Address		
Tel:	Fax:	e-mail:

1.3 Address for invoicing (if different from laboratory address on page 1)

Address		
Tel:	Fax:	e-mail

Part 2 Staff

2.1 Please list the names, technical qualifications and relevant experience of the following staff

Technical Manager for laboratory

Name	
Qualifications	
Relevant Experience	

Quality Manager for laboratory

Name	
Qualifications	
Relevant Experience	

Part 3 Scope of application: Medical Testing

3.1 List all the disciplines/parameters for which you seek accreditation in the Medical Testing Field.

DISCIPLINE/ SAMPLE TYPE	TYPES OF TESTS/PROPERTIES MEASURED RANGE OF MEASUREMENT	EQUIPMENT/METHOD /TECHNIQUE	PROFICIENCY TESTING (PT)/INTERLABORATORY COMPARISON (ILC) PROGRAMME	DATE PT STARTED AND FREQUENCY CONDUCTED

3.2 List the major items of equipment currently used for the types of test listed in 3.1

Description (include make and model)	Range/capacity of equipment and other relevant information

Part 4 Your Quality System

Please answer every question, adding comments as necessary

A: Organisation and Management

	Yes	No	Quality Manual reference/other comment
1. Is a copy of the Quality Manual supplied with this application? If "no" give reason			
2. Are policy and procedure for the operation of the organisation/ laboratory identified on the Quality Manual			
3. Are there documented procedures for control of changes to quality documentation?			
4. Does the Quality Manual contain charts showing: - the organisational structure within the laboratory? - the relationship to any parent organisation?			
5. Has the Quality Manager the responsibility and authority to identify quality problems and initiate effective solutions?			

B: Quality Audit and Review

	Yes	No	Quality Manual reference/other comment
1. Are there documented quality procedures for auditing laboratory activities?			
2. How frequently are quality audits held?			
3. Are records of quality audits maintained?			
4. Is the laboratory's quality system reviewed at regular intervals			
5. How frequently are reviews of the quality system carried out?			

C: Laboratory Staff

	Yes	No	Quality Manual reference/other comment
1. Does the Quality System contain provisions for the supervision of unqualified staff?			
2. Have the appropriate standards of professional ability, qualifications and experience been prescribed for technical managerial posts?			
3. Are documented training arrangements and records available?			

D: Equipment and Calibration

	Yes	No	Quality Manual reference/other comment
1. Does a fully documented calibration programme (as required by MAURITAS document R3) exist to ensure that the accuracy of equipment is adequate for the service operated by the organisation/laboratory?			
2. Is a record maintained for test equipment, including calibration results			
3. Are adequate facilities and environments provided for calibration, handling, control, storage and maintenance of all testing and measuring equipment?			
4. Are there documented procedures for calibrating all equipment and reference standards which cover the method of calibration, maximum intervals between calibrations and (where appropriate) the storing of equipment after calibration?			
5. Are the internal organisation/laboratory reference standards, and the calibration of key testing equipment traceable to national standards through: - MAURITAS accredited calibration laboratories? - Other bodies (specify)?			

E: Procedures

	Yes	No	Quality Manual reference/other comment
1. Are all methods and procedures for testing fully documented?			
2. Does the organisation/laboratory use any non-standard methods (eg, documented in-house methods)?			
3. Are the documents referred to above available to all concerned?			

F: Accommodation and environment

	Yes	No	Quality Manual reference/other comment
1. Are the environments in which tests are undertaken suitable for the accuracy of the determinations made?			
2. Is there control of access to work areas?			

G: Handling and storage

	Yes	No	Quality Manual reference/other comment
1. Are work and inspection instructions documented and implemented for the handling, storage and disposal of materials and samples?			
2. Is provision made to prevent deterioration or damage to materials or samples, both before and after tests?			
3. Are storage methods prescribed, including special environments?			
4. Are there prescribed procedures for the inspection of samples in storage?			
5. Are such stores accessible only to authorised persons?			

H: Records

	Yes	No	Quality Manual reference/other comment
1. Is there a prescribed system of recording test results?			
2. Are original observations and calculations recorded and stored?			
3. Are there arrangements for ensuring the accuracy, completeness and confidentiality of all records?			
4. For what period does the organisation/ laboratory retain the original recorded observations and derived data?			

J: Test reports

	Yes	No	Quality Manual reference/other comment
1. Do you have a list of authorised signatories, by name or position?			
2. Do test reports contain all the information required by ISO 15189?			

K: Complaints and anomalies

	Yes	No	Quality Manual reference/other comment
1. Do you have a documented procedure for handling complaints/anomalies?			
2. Do you keep records of complaints/-anomalies and actions taken?			

L: Referral Laboratories and Advisory services

	Yes	No	Quality Manual reference/other comment
1. Do you use referral laboratories?			
2. Do you have a register of all referral laboratories used and a record of all referred samples?			
3.Do you evaluate all referral laboratories used?			
4. Do you offer advisory services to your customers?			

M: Outside support services

	Yes	No	Quality Manual reference/other comment
1. Do you have a documented policy on the procurement of support services?			
2. Do you keep records of such suppliers?			

N: Compliance with ISO 15189 and, MAURITAS Regulations

1. Do you consider that your laboratory complies with ISO 15189 and MAURITAS Regulations?

Yes ☐ No ☐

If "no", in which areas does it not comply, and when do you expect non-compliances to be rectified?

Area of non-compliance	Rectified by (date)

Part 5 Other approvals

Please detail current approvals held by your laboratory's calibration/testing facility

Name and address of approval body	Scope of accreditation/ approval and number of certificate if any	Period of Accreditation	
		Start	Finish

Part 6 Declaration

6.0 The organisation applies for accreditation by MAURITAS in the Medical Testing Field

For extension in the schedule of existing accreditation by MAURITAS, fill in Part 1-4 above.

6.1 The organisation/laboratory agrees to implement and to comply with the requirements of ISO 15189 and MAURITAS R1, R2 and R3 and any other publication as specified by MAURITAS prior to being assessed by MAURITAS on site.

6.2 The organisation/laboratory agrees to comply, upon accreditation, with ISO 15189, MAURITAS Regulations and any other publication as specified by MAURITAS.

6.3 I enclose a copy of the Quality Manual ☐

6.4 I understand the manner in which the accreditation system functions

6.5 I declare that the information given in this form is correct to the best of my knowledge and belief

6.6 I undertake that the organisation will pay all fees due to MAURITAS in accordance with the MAURITAS fee stucture, whether or not accreditation is granted.

6.7 I enclose the application fee. (Cheques should be made payable to **"The Government of Mauritius"**).

6.8 I take note that the application form for accreditation is valid for a maximum period of **two years** as from the date of signature.

Signed :_____Date:_____

Name :_____

Position:_____

The completed form should be forwarded to the following address:

The Director
Mauritius Accreditation Service (MAURITAS)
8th Floor, Air Mauritius Centre
President John Kennedy Street
Port Louis
Mauritius
Tel: +230 208 1690
Fax: +230 210 6101

Part 7 Review of Application

For MAURITAS use only – Accreditation Manager Review of Application	
Date of receipt of Application : ...../...../.....	
Application form filled adequately	: Yes ☐ No ☐
Quality Manual submitted	: Yes ☐ No ☐
Procedures Manual submitted	: Yes ☐ No ☐
Proficiency Testing Results submitted	: Yes ☐ No ☐
Validation Data submitted	: Yes ☐ No ☐
Application Fee paid	: Yes ☐ No ☐
Application complete and all relevant documentation submitted: Yes ☐ No ☐	
Comments:	
Accreditation Manager:	Signature: .....