

# **CERTIFICATE OF ACCREDITATION**

*In terms of section 22(2) (b) of the Accreditation for Conformity Assessment, Calibration and Good Laboratory Practice Act, 2006 (Act 19 of 2006), read with sections 23(1), (2) and (3) of the said Act, I hereby certify that:-*

**INSTITUTE OF BIO RESEARCH AUDITING AND TRAINING IN  
SOUTHERN AFRICA (PTY) LTD**  
**Co. Reg. No.: 2019/195768/07**

Facility Accreditation Number: **C109**

is a South African National Accreditation System accredited facility  
provided that all SANAS conditions and requirements are complied with

This certificate is valid as per the scope stated in the accompanying scope of accreditation,  
Annexure "A", bearing the above accreditation number for

**MEDICAL DEVICES QUALITY MANAGEMENT SYSTEMS**

The facility is accredited in accordance with the recognised International Standard

**ISO/IEC 17021-1:2015**

While this certificate remains valid, the accredited facility named above is authorised to  
use the relevant accreditation symbol to issue facility reports and/or certificates

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**Mr F Osman**  
**Acting Chief Executive Officer**

**Effective Date: 31 October 2024**  
**Certificate Expires: 05 September 2027**

## ANNEXURE A

### SCOPE OF ACCREDITATION

Facility Number: **C109**

**Permanent Address of Facility:**

Institute of Bio Research Auditing and  
Training in Southern Africa (Pty) Ltd  
222 Corobay Avenue  
Waterkloof Glen  
Pretoria  
0010

**Management Signatory:**

Dr F Mashinya

**Postal Address:**

222 Corobay Avenue  
Waterkloof Glen  
Pretoria  
0010

**Nominated Representative:**

Dr F Mashinya

**Tel:** 078 437 0712

**E-mail:** Felistas.mashinya@ibratsa.co.za

**Issue No.:**

05

**Date of Issue:**

07 April 2026

**Expiry Date:**

05 September 2027

Institute of Bio Research Auditing and Training Southern Africa (Pty) Ltd complies with the accreditation criteria for certification bodies as laid down in ISO/IEC 17021-1:2015 and authorised to certify organisations to ISO 13485:2016 (Medical Devices Quality Management Systems-Requirements) in the following industrial sector:

| Main Technical Areas                           | Technical Area                                                                                                                                                                                                                                                                                                                              |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| A1.1 Non-Active Medical Devices                | Non-active implants                                                                                                                                                                                                                                                                                                                         |
| A1.4 In Vitro Diagnostic Medical Devices (IVD) | Reagents and reagent products, calibrators and control materials for: <ul style="list-style-type: none"> <li>Clinical chemistry</li> <li>Immunochemistry (Immunology)</li> <li>Haematology/Haemostasis/Immunoematology</li> <li>Microbiology</li> <li>Infectious Immunology</li> <li>Histology/Cytology</li> <li>Genetic Testing</li> </ul> |
| A1.7 Parts and Services                        | In Vitro Diagnostic Instruments and software<br>Maintenance services<br>Other services-Decontamination of devices<br>Distribution services                                                                                                                                                                                                  |

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Original date of Accreditation: 06 September 2022

ISSUED BY THE SOUTH AFRICAN NATIONAL ACCREDITATION SYSTEM

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**Accreditation Manager**