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CAB Number: C0109

**The Institute of Bio Research Auditing and Training in Southern Africa (IBRATSA)**

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Attention: Dr F Mashinya

**OUTCOME LETTER: LETTER OF RECOGNITION FOR IBRATSA AS A CERTIFICATION BODY FOR ISO 13485**

1. The South African Health Products Regulatory Authority (SAHPRA) has reviewed your application in terms of the Medicines and Related Substances Act for Recognition as a conformity assessment body in South Africa.
2. This letter serves to confirm that the Institute of Bio Research Auditing and Training in Southern Africa (IBRATSA), based in Pretoria bearing a SANAS accreditation number, **C0109**, has been accredited in line with ISO/IEC 17021-1:2015 and is hereby authorised to certify organisations to ISO 13485:2016 – Medical Devices Quality management Systems requirements.
3. The regulatory authority recognizes and approves the above Conformity assessment body.

The above Conformity assessment body will be included in database and published on the website.

Yours faithfully,

Digitally Signed by:  
Dimakatso Mathibe  
Senior Manager Medical Device Unit  
2b3e99b2-7995-4853-a388-d5e71a63c255

**Dr Dimakatso (Theresa) Mathibe, PhD, MBL**

**Senior Manager Medical Device Unit**

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