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DEKRA Certification B.V.

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Attention: Vincenzo Lanzillotti

OUTCOME LETTER: LETTER OF RECOGNITION FOR DEKRA Certification B.V. 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 **DEKRA Certification B.V.**, based in Netherlands bearing a accreditation certificate number , **C589** has been accredited in line with ISO/IEC 17021-1:2015 and as Auditing Organization under the Medical Device Single Audit Program (MDSAP) ; is hereby authorised to certify organisations to ISO 13485:2016 – Medical Devices Quality management Systems requirement in South Africa .
3. The regulatory authority recognizes and approves the above Conformity assessment body .
4. The above Conformity assessment body will be included in database and published on the website .

Yours faithfully,

Dimakatso Mathibe

SIGNFLOW

Dr Dimakatso (Theresa) Mathibe, PhD, MBL

Senior Manager Medical Device Unit

Date: