MEDICINES CONTROL COUNCIL MEDISYNEBEHEERRAAD

Republic of South Africa Private Bag X828 PRETORIA 0001



IKANSELE ELAWULA UKUSETSHENISWA KWEMITHI KHANSELE TAOLO YA DIHLARE

Republiek van Suid-Afrika Privaat Sak X828 PRETORIA 0001

The Authorised Representative

Obsidian Health (Pty) Ltd Cosmo Business Park Malibongwe Drive, Randburg Gauteng 2188

Fax: 086 687 5384

Email: dennisb@obsidianhealth.co.za

Dear Sir/Madam,

RE: APPLICATION FOR A LICENCE BY A **MEDICAL DEVICE ESTABLISHMENT** IN TERMS OF SECTION 22C (1) (b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, (Act101of 1965)

- 1. I acknowledge receipt of your application for licensing of your Medical Device Establishment in terms of the provisions of sub-section 22C (1)(b) of the Act.
- 2. I have processed your application and shall submit it to the Medicines Control Council for a determination.
- 3. In the event of success, the licence will be issued to you.
- 4. The Council may request further information (sub-section 22C (3)) if there are any deficiencies identified. You are kindly requested to respond promptly.
- 5. Where Council decision is to not approve your application you will be furnished with reasons.

Yours faithfully

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REGISTRAR OF MEDICINES

DATE: 26 July 2017