

## Silentium Tech receives regulatory approval from SAHPRA to bring new tinnitus treatment, Cleanhearing Sono, to South Africa.

Friday 3 February, 2023

Silentium Tech has received approval from the South African Health Products Regulatory Authority (SAHPRA) to import a new tinnitus treatment, developed by European manufacturer, Cleanhearing GmbH. Cleanhearing Sono is approved as a Class IIa medical device for tinnitus in the EU and UK and will be available in South Africa from February 2023.

Tinnitus, or 'ringing in the ears' is a symptom of disturbance in the auditory system, often caused by hearing loss, exposure to loud noise, head trauma or certain medications. According to the South African Association of Audiologists, tinnitus affects between 15% and 35% of people globally with an estimated 20 million in South Africa alone. Despite its prevalence treatment options for tinnitus are limited and usually focus on masking or coping rather than treating the underlying causes. Many patients are even told that they have no option but to learn to live with the condition.

In response to this problem, Silentium Tech has applied successfully for regulatory approval to make the Sono medical device available to patients and clinicians in South Africa. The device helps patients treat and manage their tinnitus at home, targeting underlying causes for long term relief rather than masking or habituation. Twice daily treatments of up to 20 minutes are recommended with benefits including reduced tinnitus noise and occurrence and improved sleep and mood. Results are typically seen within two to four months of regular use.

To use Sono, patients simply put on the comfortable headphones and follow the prompts on the intuitive handheld controller. Special coils inside the headphones deliver gentle electromagnetic pulses that target underlying physiology and changes linked to tinnitus. Sono treatment is quiet and calming and is designed to encourage deep relaxation. Additional features include a choice of settings and smartphone pairing so users can add notched music therapy, masking files or calming music, which are all available on the Cleanhearing tinnitus app.

Silentium Tech founder, Tasnim Dawood, is a Durban-based audiologist and specialist in vestibular disorders. She sees many patients who are actively seeking help for tinnitus. "Sono appealed to us because electromagnetic stimulation is a safe, non-invasive technology that is shown to be effective for tinnitus. Sono makes it easily accessible for both patients and clinicians. Another advantage is the flexibility for clinicians to adapt and tailor Sono treatment, for example by using the notched music option to create an enhanced two-in-one therapy for suitable patient groups."

Tasnim is joined in the enterprise by her husband and business partner, Adnan. "Our mission has been to identify state-of-the-art technologies that can improve life quality and help patients and clinicians manage this distressing condition. We are delighted that the SAHPRA approval means we can now introduce this innovative medical device to the tinnitus community in South Africa."

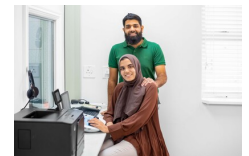
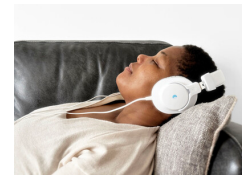
Sono is available in South Africa from February 2023. Silentium Tech is inviting enquiries from interested partner clinics. Please contact [admin@silentiumtech.co.za](mailto:admin@silentiumtech.co.za)

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