PRESS RELEASE

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Allerød, Denmark, 15 September, 2026

Cebreo Medical receives CE mark for NeuroBuds®, a discreet in-ear, medical-grade EEG wearable for extended ambulatory monitoring

The Danish medtech company's ear-EEG platform can now be placed on the European market, enabling clinicians to record multi-day and multi-night EEG in the patient's home for epilepsy, sleep and other neurophysiological research and care.

Cebreo Medical A/S today announced that its NeuroBuds® device has received CE marking, confirming conformity with the applicable EU requirements for placing the device on the European market. Cebreo Medical is a Danish medical technology company developing wearable EEG solutions for real-world neurophysiological monitoring. The milestone allows Cebreo Medical to move from clinical research use toward broader availability of NeuroBuds to hospitals, neurological and sleep clinics and research sites across Europe.

NeuroBuds is a non-invasive, CE-marked medical device — a wearable that enables longitudinal assessment of epilepsy, sleep physiology and other neurophysiological outcomes in real-world settings. Unlike conventional EEG systems that require a technician-applied cap of electrodes, NeuroBuds is designed to be used unassisted by the patient at home, enabling multi-day and multi-night recordings in a patient's daily life environment.

> *"With NeuroBuds, we can for the first time offer a discreet, unobtrusive solution that enables long-term, unassisted EEG monitoring for weeks at a time, in patients' own homes and daily lives. The product has the potential to significantly reduce the cost of long-term EEG monitoring and strengthen treatment decisions compared with conventional brain monitoring."*
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> **— Rasmus Elsborg Madsen, CEO, Cebreo Medical**

Designed to resemble a hearing aid rather than conspicuous clinical monitoring equipment, NeuroBuds is built to minimize the stigma and burden that typically limit compliance in long-term EEG monitoring. Because it is comfortable and simple enough for unassisted use, it supports monitoring periods of up to three months, with repeat measurements — generating the kind of real-world, day-to-day and night-to-night data that is difficult and costly to obtain with conventional monitoring equipment.

Built on more than fifteen years of research combined with hearing-aid engineering heritage

NeuroBuds combines a dedicated recorder with Cebreo Medical's fit-for-purpose in-ear electrode array in a single, discreet headset, enabling continuous acquisition of real-world EEG data across day and night. The solution builds on more than 15 years of research and development in collaboration with leading scientists. It also draws on engineering expertise originating from one of the world's largest hearing aid manufacturers, following established medical-grade design and manufacturing principles across the EU and US. As a non-invasive, low-burden technology, NeuroBuds carries a documented safety and tolerability profile supporting long-term, unassisted use.

> *"When we published our first work on ear-EEG around fifteen years ago, it was an open question whether signals recorded from the ear could have meaningful clinical applications. Our collaboration with Cebreo Medical has since demonstrated the clinical potential of ear-EEG across several indications. I am very happy to see Cebreo Medical reach CE marking of the NeuroBuds, and I look forward to seeing this technology make its way into clinical practice."*
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> **— Prof. Preben Kidmose, Department of Electrical and Computer Engineering, Aarhus University**

Extending EEG monitoring beyond the hospital

Extended, ambulatory EEG monitoring has relevance well beyond a single condition — from epilepsy to sleep medicine and other areas of neurophysiological research. Drug-resistant epilepsy is one clear example: treatment decisions for these patients depend on an accurate, longitudinal picture of seizure frequency and treatment response, something that is difficult to obtain from traditional monitoring.

> *"For patients with drug-resistant epilepsy, the question is not whether they have seizures — it's how often, and whether a new treatment is actually working. Patient-reported seizure counts are often unreliable, particularly for subtle or nocturnal seizures patients don't even notice. An ambulatory ear-EEG device that can run for weeks at a time, in the patient's own daily life, provides the EEG data with the potential to objectively quantify the seizure burden, and hence, more properly evaluate treatment."*
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> **— Prof. Sandor Beniczky, Department of Clinical Neurophysiology, Rigshospitalet; Danish Epilepsy Centre**

A full-service platform, not just a sensor

Meeting this need — whether in epilepsy, sleep or other areas of neurophysiological research — takes more than a wearable sensor. Cebreo Medical operates a full-service EEG acquisition and analysis platform combining wearable hardware, a patient app for onboarding and secure data transfer, compliant cloud infrastructure, a study oversight portal, and expert human review. The Cebreo Medical analytics framework is developed by a multidisciplinary team of PhD-level data scientists in signal processing, machine learning and clinical neurophysiology. Accredited somnologists and EEG experts provide human-in-the-loop quality control, sleep staging verification and clinical interpretation, helping ensure the data is suitable for regulatory-grade evidence generation. Cebreo Medical's work is grounded in long-standing academic collaboration, including with Prof. Poul Jennum and the Danish Center for Sleep Medicine.

> *"There is an unmet need to make diagnostic testing more accessible for our patients. Today, many who would benefit from extended sleep monitoring simply never get it, because current equipment is too cumbersome to use and only allows point measurements — and hospital and clinic EEG resources are already stretched thin. What this field needs is a simpler, non-invasive way to monitor patients continuously, ideally from the comfort of their own home environment."*
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> **— Prof. Poul Jennum, Danish Center for Sleep Medicine, Rigshospitalet**

What's next

With CE marking secured, Cebreo Medical will focus on expanding commercial availability of NeuroBuds across European research and clinical sites, alongside its ongoing work with pharmaceutical and academic partners on decentralized, longitudinal EEG studies in epilepsy, sleep and other neurophysiological research. The company is also advancing its regulatory pathway for the US market.

About Cebreo Medical

Cebreo Medical A/S is a Danish medical technology company developing wearable EEG solutions for extended, real-world neurophysiological monitoring, currently focusing on epilepsy, sleep and other neurophysiological research. Combining medical-grade wearable hardware, a cloud-based analytics platform and human-in-the-loop clinical review, Cebreo Medical enables researchers, clinicians and pharmaceutical partners to capture objective, longitudinal EEG data outside the hospital — supporting evidence generation, digital biomarker development and decentralized clinical research. Cebreo Medical is wholly owned by T&W Medical A/S and is based in Allerød, Denmark, just north of Copenhagen. Learn more at www.cebreomedical.com.

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