Headsafe Receives MDSAP Certificate of Registration to Support International Expansion

Milestone strengthens pathway into Australia and supports future market access opportunities in Japan, Brazil, and Canada.

LAKE MARY, FL, UNITED STATES, May 19, 2026 /EINPresswire.com/ -- Headsafe, an Australian medical technology company with offices in Sydney, Australia, and Headquarters in Lake Mary, Florida, USA, today announced that Headsafe MFG Pty Ltd. has received a Medical Device Single Audit Program, MDSAP, Certificate of Registration from Intertek, an MDSAP-recognized auditing organization. The certificate confirms conformance to ISO 13485:2016 and supports regulatory requirements for Australia and the United States.

This milestone strengthens Headsafe's international commercialization strategy by supporting a more efficient regulatory pathway into other priority markets outside of the United States. Australia is the company's home market, Headsafe expects this progress to support their application for a Conformity Assessment Certificate with the Therapeutic Goods Administration, TGA, allowing for commercial activities to commence in Australia by quarter three 2026.

MDSAP also creates a foundation for future market entry in Japan, Brazil, and Canada, all of which recognize the program as part of their medical device regulatory framework. Headsafe plans to evaluate those opportunities over time, based on strategic priorities, market readiness, and commercial fit.

"Nurochek was built to bring objective brain data into real-world clinical decision-making, this milestone helps us expand that mission beyond the U.S.," said Craig Corrance, Chief Executive Officer of Headsafe. "Australia is a logical next step for the business. It has a strong healthcare system, a clear regulatory pathway, and a growing need for practical tools that support more confident concussion assessment."

The Australian MedTech market was valued at approximately US $8.5 billion in 2024/5 and represents an attractive market for Headsafe due to its advanced healthcare infrastructure, strong public investment in medical innovation, and established pathways for adoption of new medical technologies. The Company expects to use this regulatory progress to support commercial planning and market development activities in the antipodean region.

“This certification reflects disciplined work across our quality and regulatory systems,” said Philip Gower, Chief Strategy and Commercial Officer, Headsafe. “It also marks an important step in building Headsafe as a global brain health company. Our goal is to help clinicians access objective concussion assessment tools that fit the realities of frontline care.”

Headsafe’s flagship product, Nurochek™, is an FDA-cleared portable EEG system that provides objective brain function data as an aid to the diagnosis of concussion, as a consequence of mild traumatic brain injury. Using visual evoked potentials, VEPs, the system rapidly generates and analyzes brain-response data and delivers results in approximately two minutes. Nurochek™ does not require a baseline test, allowing clinicians to assess patients without prior data on file.

The Company is focused on supporting adoption across healthcare settings where concussion evaluation can be time-sensitive and difficult to standardize, including emergency medicine, urgent care, sports medicine, and other clinical environments.

About Headsafe
Headsafe is a MedTech company headquartered in Sydney, Australia, with a growing U.S. presence. Its mission is to make concussion assessment faster, safer, and more consistent across points of care.

The company’s flagship product, Nurochek™, is a portable, FDA-cleared brain assessment device used as an aid to the diagnosis of concussions that delivers objective brain function data in approximately two minutes, without requiring a baseline test. Designed for use in emergency departments, urgent care, neurology clinics, and sports medicine settings, Nurochek™ is intended for use in healthcare facilities.

With U.S. and Global Operations led by CEO Craig Corrance, Headsafe is focused on supporting real-world adoption through practical implementation, training, and clinical workflow integration.

Media Contacts
For press inquiries, please contact info@headsafe.com or visit www.headsafe.com.

Important Use Information
Nurochek™ is FDA-cleared as an aid in the diagnosis of mild traumatic brain injury, mTBI, concussion when used in conjunction with a standard neurological assessment. It is cleared for patients ages 12 to 44 years old, within 120 hours, 5 days of a potential head injury, and is intended for prescription use in healthcare facilities or by healthcare professionals. Exclusion criteria apply, including seizure history, epilepsy, existing structural brain injuries, and legal blindness.

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