

5 October 2026

NeuroStrip CE Marked for Sale Across Europe

EU Declaration of Conformity issued for NeuroStrip as a Class I medical device under the EU Medical Device Regulation, enabling supply across the European Union, the European Economic Area and Northern Ireland.

Control Bionics Limited (ASX: CBL) (Control Bionics or the Company) advises it has been issued an EU Declaration of Conformity for NeuroStrip, its wearable surface electromyography (sEMG) device, under the EU Medical Device Regulation 2017/745 (EU MDR).

Highlights

- NeuroStrip meets the requirements of the EU MDR as a Class I medical device and is now CE marked.
- Registration of NeuroStrip was completed on 2 October 2026 and is registered in the European Database on Medical Devices (EUDAMED).
- CE marking allows NeuroStrip to be placed on the market in 27 EU member states, Iceland, Liechtenstein, Norway and Northern Ireland, a combined population of more than 450 million
- NeuroStrip now has regulatory registrations in the US, Great Britain and the EU. An application to Australia's Therapeutic Goods Administration (TGA) is pending.

Control Bionics CEO and Managing Director Jeremy Steele said: "Europe is home to some of the world's largest clinical rehabilitation, sports science and research communities, where customers and partners expect an established regulatory foundation before adopting a new platform. With the US, Great Britain and the EU now in place, our focus is on rapidly building our customer and partner base."

What CE marking means

CE marking enables NeuroStrip, together with the NeuroStrip app, already available through the Apple App Store, Mac App Store and Microsoft Store, to be supplied to clinicians, rehabilitation providers, researchers and sports organisations across Europe.

Under the EU MDR, NeuroStrip is classified as Class I medical device, reflecting its intended purpose as a non-diagnostic sEMG measurement and biofeedback tool. Class I devices are CE marked on the basis of an EU Declaration of Conformity issued by the manufacturer, confirming the device meets the general safety and performance requirements of the EU MDR. Review by a Notified Body is not required for Class I devices, and CE marking is not

an approval or clearance granted by a European regulator. NeuroStrip is categorised under European Medical Device Nomenclature (EMDN) code Z12062401 (electromyographic biofeedback systems).

Control Bionics is registered as a manufacturer in the European Commission's database on medical devices, under Single Registration Number US-MF-000043550.

NeuroStrip Regulatory Position 5 October 2026

Market	Status	Date
United States	FDA establishment registration and device listing	August 2026
Great Britain	MHRA manufacturer and device registration. UKCA marking	6 August 2026
European Union, EEA and Northern Ireland	EU MDR Declaration of Conformity issued. Class I. Registration completed	2 October 2026
Australia	TGA application submitted, ARTG inclusion pending	Submitted

Authorisation

This announcement has been authorised for release to the ASX by the Board of Control Bionics Limited.

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About Control Bionics

Control Bionics Limited is a neurotechnology company commercialising objective, non-invasive neural-signal technology proven in clinical environments and built to scale across multiple markets. Its neural-signal platform captures the body's physiological signals, including the electrical activity generated by muscles, with medical-grade precision and converts them into measurable, decision-ready outcomes. A single underlying technology platform serves four applications: Performance, Rehabilitation, Research & Data, and Assistive Communication. The technology has historically been deployed in assistive communication and is now being extended into sports performance, rehabilitation, medical research, platform partnerships and broader human-computer interface applications. Control Bionics' technology does not require surgery or implantation, and holds regulatory clearances in the US, Australia and Europe. The Company is also a registered NDIS provider in Australia.

