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Bittele Electronics Achieves ISO 13485:2016 Certification for Malaysia Facility

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Content

TORONTO, ON — Bittele Electronics announced that its Malaysia manufacturing facility, Bittele Electronics Sdn. Bhd., has achieved ISO 13485:2016 certification for medical device manufacturing quality management systems. The certification covers the manufacturing of printed circuit board assemblies for medical devices, including Flash Stimulator Modules for EEG devices and respiratory effort sensors (Maxxi Rip Sensor).

Located in Pulau Pinang, Malaysia, the facility received certification under registration number 600371, valid from May 19, 2026 through May 18, 2029. “This certification reflects Bittele’s continued commitment to quality, regulatory compliance, and reliable medical electronics manufacturing,” said Ben Yang, CEO of Bittele Electronics. “It also expands our global ISO 13485-certified manufacturing capabilities and provides customers with greater supply chain flexibility.”

ISO 13485:2016 is the internationally recognized quality management standard for medical device manufacturing, requiring strict controls for traceability, risk management, and production consistency.

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Tags:

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About Us:

Heading : About Bittele Electronics

Bittele Electronics is a Canadian electronics manufacturing company specializing in turnkey PCB fabrication and assembly services for prototype and low-to-mid volume production. Founded in 2003, the company serves clients across industries including technology, automotive, healthcare, and consumer electronics, with operations in Canada, Malaysia, and China.