(Company Registration No.: 200909384G)

FOR IMMEDIATE RELEASE

AZTECH GLOBAL SECURES FDA REGISTRATION FOR ITS MALAYSIA FACILITY, STRENGTHENING ITS POSITION AS A MANUFACTURING PARTNER FOR MEDICAL DEVICE OWNERS FOR THE US MARKET

SINGAPORE, 22 January 2026 - SGX Mainboard-listed Aztech Global Ltd. ("Aztech") is proud to announce that its wholly-owned Malaysia manufacturing facility, **IOT Manufacturing Sdn. Bhd. ("IOTM")** has received its **Certificate of Registration** under the **U.S. Food and Drug Administration's ("FDA")** 21 CFR Part 807[1] Establishment Registration and Device Listing ("21CFR807"). Located in Pasir Gudang, Johor, Malaysia, **IOTM is also ISO 13485 certified**, reinforcing Aztech's readiness to serve as a scalable, compliant and preferred manufacturing partner for medical device owners seeking accelerated entry to the United States ("U.S.") market.

"Medical device owners increasingly need manufacturing partners who can deliver speed without compromising compliance," said **Mr. Michael Mun, Executive Chairman and CEO of Aztech Global Ltd.** "With FDA establishment registration under 21 CFR Part 807 and our established track record in manufacturing IoT products for the U.S. market, Aztech is well-positioned to help customers accelerate their journey — from industrialisation and production through to commercial supply and end-market delivery."

Aztech as Preferred Medical Device Manufacturer for Rapid Entry into the U.S. Market

IOTM is a 300,000 square feet manufacturing facility situated on approximately 9.11 acres of land. Since 2023, it has supported the manufacturing and vertically integrated packaging needs of global IoT product owners. Leveraging state-of-the-art production capabilities and the expertise of Aztech's three R&D centres, the facility delivers seamless solutions from product design through commercial-scale manufacturing.

[1] According to FDA.Gov (30 Sep 2025), owners or operators of establishments involved in the production and distribution of medical devices intended for use in the United States are required to register annually with the FDA under the Code of Federal Regulations (CFR). This requirement is set out in 21 CFR Part 807, which governs FDA establishment registration and device listing.

With its ISO 13485 certification and 21CFR807, IOTM is purpose-built and ready to support medical device owners seeking to:

- **Reduce time-to-market** by engaging a manufacturing partner already registered under 21CFR807, a mandatory requirement for manufacturing, importing, and marketing medical devices in the U.S.
- **Assurance of device quality** through production under an ISO 13485–certified quality management system
- **Scale production reliably and globally** through a mature manufacturing footprint backed by a Singapore-listed company with an established vertically integrated global network
- **Diversify supply chains** and leveraging Malaysia's position as a highly export-oriented medical device manufacturing hub — with over 90% of locally manufactured medical devices exported and **more than half going to major markets including the U.S.**, underlining the country's strategic role in global MedTech supply chains[2].

Leveraging the U.S.–Malaysia Trade Synergy for the World's Largest MedTech Market

Demand trends - The U.S. remains the world's largest medical device market, representing over 40% of global MedTech demand. In 2024, the U.S. medical device market was valued at approximately SGD242.3 billion (US$188.7 billion)[3], underscoring the continued need for compliant and scalable manufacturing partners to support market expansion[4].

Supply trends - Malaysia continues to strengthen its role in global MedTech supply. In 2024, Malaysia's medical device exports to the U.S. accounted for nearly 37% of its total global medical device exports[5]. Malaysia remains a strategic base for global MedTech and this momentum is underpinned by its advanced industrial infrastructure and international port connectivity that support efficient global supply.

[2] Source: ASEAN Briefing, Malaysia's Healthcare Sector: A Rising Giant in ASEAN (2024).
[3] Currency conversion rate is based on an estimated rate of US$1:SGD1.2841
[4] Source: U.S. Medical Devices Market Size, Share & Forecasts 2024–2032, Fortune Business Insights
[5] Source: The Star / Asianews report on Malaysia's medical device exports to the U.S. in 2024.

Aztech's One-Stop Manufacturing Platform for Your Global MedTech Expansion

With continued investments in advanced manufacturing technologies and regulatory-compliant processes, strategically located manufacturing facilities, and a proven track record of delivering high-quality IoT products for global markets, Aztech is well positioned to support medical device owners across the full U.S. market lifecycle.

Aztech's **integrated medical device manufacturing ecosystem** includes:

- FDA aligned quality management systems
- Controlled environment production
- Precision engineering and automated assembly
- Design for manufacturing ("DFM") and prototyping support
- Comprehensive testing and validation capabilities

This milestone reinforces Aztech's long-term strategy to expand its global MedTech manufacturing footprint and serve as a scalable, compliant and trusted partner for medical device owners seeking accelerated entry and growth in the U.S. market.

Regulatory Note:

FDA Establishment Registration and Device Listing under 21 CFR Part 807 provides the FDA with information about medical device establishments and their activities. It is distinct from, and does not itself constitute, FDA marketing authorisation or clearance/approval for any specific device.

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About Aztech Global Ltd. www.aztechglobal.com

Aztech Global Ltd. (stock code: 8AZ) together with its group of companies ("Aztech") is a designer and manufacturer of IoT devices and data-communication products across diverse market segments including security, consumer, communications, health-tech, industrial and automotive. Supported by its comprehensive suite of design, engineering, and manufacturing services, Aztech prides itself as the key technology enabler across its clientele base that ranges from blue chip customers to technological start-ups with innovative products.

Headquartered in Singapore, Aztech traces its roots to a group founded in 1986. It operates three R&D centres in Singapore, Hong Kong and Shenzhen, China and two manufacturing facilities in Dongguan, China and Johor, Malaysia, supported by a workforce of about 2,000. Its manufacturing facilities are ISO 9001-, 13485-, 14001-,

45001- and IATF 16949-certified demonstrating Aztech's commitment to quality and compliant products, workplace safety and environmental responsibility. The Malaysia facility is also U.S. FDA-registered under 21 CFR 807, strengthening Aztech's ability to manufacture medical devices that require stringent regulatory compliance.

Recognising that a thriving community and resilient climate contributes to long-term business resilience, Aztech supports initiatives that promote inclusion, entrepreneurship, and climate resiliency. Its commitment to business excellence, ESG and governance has also been endorsed with awards and accolades. The list includes The Enterprise Award at the Singapore Business Awards 2025, The Edge Singapore Centurion Club 2024 Award - Highest Growth in Profit After Taxes over Three (3) Years" for the Software & IT Services and Technology Equipment sector, Investors' Choice Awards 2024 Singapore Corporate Sustainability Award (Mid Cap Category) and Most Transparent Company Award (Technology Category) by SIAS, Singapore's Best Managed Companies 2024 and 2025 by Deloitte, 200 Best Under a Billion 2024 and Special Award – Best Return on Equity by Forbes Asia, Fortune SEA 500 company in 2024 and 2025, Singapore's Fastest Growing Companies from 2023 to 2025 by the Straits Times, and Asia Pacific's High-Growth Companies 2024 by the Financial Times.

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