AJJ MEDTECH HOLDINGS LIMITED
(Company Registration No. 198403368H)
(Incorporated in the Republic of Singapore)

BUSINESS UPDATE:
HSA CLASS C REGISTRATION AND ISO 13485 DESIGN & MANUFACTURING SCOPE EXPANSION FOR HEMODIALYZER, SUPPORTING SINGAPORE COMMERCIALISATION AND INTERNATIONAL MARKET DEVELOPMENT

The Board of Directors (the "Board") of AJJ Medtech Holdings Limited (the "Company", and together with its subsidiaries, the "Group") is pleased to announce two complementary milestones relating to the Group's sterile hollow fiber hemodialyzer: (i) **HSA Class C product registration in Singapore on 9 September 2026**, supporting regulatory market access and commercialisation of the registered product in Singapore; and (ii) an **ISO 13485 scope expansion expressly covering design and development, manufacture, storage and distribution**. **Together, these milestones strengthen the Group's Singapore commercialisation, international market-development strategy and AJJ-controlled regulated MedTech platform.**

1. HSA Class C Registration and Singapore Commercialisation

On 9 September 2026, the Group obtained **HSA Class C product registration in Singapore** for the sterile hollow fiber hemodialyzer. The registration establishes the regulatory basis for the registered product's **Singapore commercialisation and market-development activities**, subject to applicable regulatory, licensing and supply requirements.

HSA Registered Product: AJJ Hollow Fiber Hemodialyzer
HSA Registration No.: MDPR260909K0003
HSA Registrant: AJJ Healthcare Management Pte. Ltd. (wholly-owned subsidiary of AJJ Medtech Holdings Limited)
Product Owner: AJJ Healthcare Management Pte. Ltd. (wholly-owned subsidiary of AJJ Medtech Holdings Limited)
Registered Product Family: 22 models under the Class C registration
Low Flux Series (11 models): AJJ-14L, AJJ-15L, AJJ-16L, AJJ-17L, AJJ-18L, AJJ-19L, AJJ-20L, AJJ-21L, AJJ-22L, AJJ-23L, AJJ-24L
High Flux Series (11 models): AJJ-14H, AJJ-15H, AJJ-16H, AJJ-17H, AJJ-18H, AJJ-19H, AJJ-20H, AJJ-21H, AJJ-22H, AJJ-23H, AJJ-24H
Current Legal Manufacturer Status: AJJ Healthcare Management Pte. Ltd. has achieved the Group's strategic objective of Legal Manufacturer status for selected products. For AJJ Hollow Fiber Hemodialyzer, the HSA registration identifies AJJ Healthcare Management Pte. Ltd. as both Product Owner and Registrant and does not separately designate a Legal Manufacturer field.

According to the latest available **Singapore Renal Registry Annual Report 2024** published by the National Registry of Diseases Office, Singapore recorded **9,422** resident prevalent dialysis patients as at end-2024, of whom **87.2% received haemodialysis**; **81.0% of incident dialysis patients in 2024** commenced haemodialysis; and **95.9% of haemodialysis patients** underwent treatment **three times weekly**. These statistics indicate a substantial and recurring renal-care treatment segment in Singapore,

with ongoing demand for regulated hemodialysis consumables, product quality consistency, traceability and continuity of supply.

Source: National Registry of Diseases Office, Singapore Renal Registry Annual Report 2024, published 2 June 2026.

With HSA registration in place, the registered product has entered the Group's Singapore commercial-execution phase. The Group's immediate execution priorities are **customer qualification, institutional procurement engagement and the conversion of regulatory market access into commercial opportunities in Singapore**.

The hemodialysis consumables market is currently **dominated by established international suppliers**. The Group believes that the HSA Class C registration and ISO 13485 design and manufacturing scope expansion represent an **important milestone in establishing AJJ's international hemodialysis business**. The Group intends to use **Singapore as a regulatory, commercialisation and market-development base** to enter **regulated hemodialysis markets in other countries and regions**, **compete with established international suppliers**, and build an **AJJ hemodialysis product and supply platform** supported by **design, manufacturing, quality-system and regulatory capabilities**, providing healthcare institutions with **more competitive, diversified and sustainable product and supply choices**. The Group believes that this strategy will help expand AJJ's presence in the international renal-care market, **establish a competitive alternative source of supply**, and further strengthen the Group's **control over product design, manufacturing, regulatory access and the medical-device value chain**.

2. ISO 13485 Design & Manufacturing Scope Expansion

The Board is also pleased to announce that the Company's wholly-owned subsidiary, **AJJ Healthcare Management Pte. Ltd.**, has obtained an ISO 13485 scope expansion in relation to the following scope:

Certified Entity: AJJ Healthcare Management Pte. Ltd.
Certification Standard: ISO 13485:2016
Certification Body: BSI Group Singapore Pte Ltd
SAC Accreditation: Singapore Accreditation Council (SAC) Accredited Certification Body, MDQMS-2023-07
Certificate No.: MD 827028
Date of Issue: 01 Jul 2026
Certified Scope: "Design and development, manufacture, storage and distribution of Sterile Hollow Fiber Hemodialyzer."

The ISO 13485:2016 certification is issued by **BSI Group Singapore Pte Ltd**, with the certification bearing the **Singapore Accreditation Council (SAC) Accredited Certification Body** mark (**MDQMS-2023-07**). The certified scope expressly includes **Design and Development and Manufacture**, in addition to storage and distribution, for sterile hollow fiber hemodialyzer products. This strengthens the Group's certified quality-management capabilities across core product lifecycle activities, including design control, manufacturing quality-system control, process validation, product release and traceability.

3. Commercial Execution and Product Ownership Strategy

The HSA Class C registration establishes a **Singapore commercial pathway** for the registered device, while the ISO 13485 scope expansion provides a **certified quality-management framework for design, development and manufacturing activities**. Together, these milestones strengthen AJJ's execution position in regulated MedTech.

AJJ Healthcare Management Pte. Ltd., the Company's wholly-owned subsidiary, is both the HSA Registrant and Product Owner for AJJ Hollow Fiber Hemodialyzer (MDPR260909K0003), is the ISO 13485:2016 certified entity for the expanded scope including Design and Development and Manufacture, and holds Design Authority for the registered 22-model product family. For the purposes of the Group's product-governance framework, Design Authority means final approval authority over the product's intended use, specifications, design changes, verification and validation, risk management, labelling and product claims. The Group has also achieved its strategic objective of **Legal Manufacturer status for selected products through AJJ Healthcare**. These current ownership, regulatory, design-authority, certification and Legal Manufacturer positions place AJJ Healthcare at the centre of the Group's product-control framework. The operating model is centred on:

1. product definition, intended use and claims control;

2. design and development control, including design inputs, outputs, review, verification and validation;

3. technical documentation, product specifications and risk management control;

4. design change control and design transfer;

5. manufacturing quality-system and supplier control;

6. manufacturing process control, process validation, product release and batch traceability;

7. post-market surveillance, complaint handling and corrective and preventive action (CAPA); and

8. product lifecycle and regulatory change management.

Sterile hollow fiber hemodialyzer products are Class C medical devices in Singapore and are subject to applicable product registration, quality, design verification and validation, risk-management, sterilisation, manufacturing and post-market requirements.

The Group will pursue commercialisation of the registered product in Singapore while leveraging its established product ownership, Design Authority and Legal Manufacturer framework to further strengthen AJJ's design, manufacturing and lifecycle-control capabilities.

4. Advancing into Highly Specialised, Higher-Barrier Regulated MedTech

The Group has established and continues to strengthen its medical-device manufacturing, quality-management and regulatory capabilities. Building on this foundation, the Group is advancing further into **highly specialised, highly regulated, technically demanding and higher-barrier MedTech categories**. The HSA Class C registration of the sterile hollow fiber hemodialyzer, together with the ISO 13485 scope expressly covering **Design and Development and Manufacture**, represents an **important milestone and concrete demonstration** of this strategic direction.

The sterile hollow fiber hemodialyzer represents a **tangible proof point** of AJJ's ability to apply its established manufacturing, quality and regulatory capabilities to a **specialised Class C medical-device category** with demanding requirements for quality consistency, process validation, traceability and regulatory compliance.

The Group believes that this strategic direction will enable AJJ to participate more deeply in **higher-value activities within the regulated medical-device value chain**, including product design, manufacturing, quality governance and regulatory access, while providing a foundation for expansion into **additional renal-care and other specialised medical-device categories**.

5. No Assurance and Cautionary Statement

Shareholders and potential investors should note that the HSA Class C product registration and ISO 13485 scope expansion are **regulatory and quality-management milestones supporting market access, commercialisation and the Group's product-ownership strategy.** These milestones do not by themselves determine the timing or scale of any financial contribution to the Group. They do not constitute a revenue or profit forecast, customer procurement commitment, market acceptance or assurance of future financial performance.

Any future expansion of the Group's existing Product Owner, Design Authority and Legal Manufacturer model to additional products or jurisdictions will be undertaken in accordance with applicable regulatory requirements. Commercial outcomes will depend on market demand, customer procurement, regulatory compliance, production and supply capabilities, pricing, margins and execution. The Company will make further announcements as and when there are material developments in accordance with the applicable listing rules.

6. Shareholders' Caution

Shareholders and potential investors are advised to exercise caution when dealing in the shares of the Company. Persons who are in doubt as to the action they should take should consult their stockbrokers, bank managers, solicitors, accountants or other professional advisers.

BY ORDER OF THE BOARD

Dr Tan Wei Jie
Chief Executive Officer and Executive Director

Date: 11 Sep 2026
