

Memphasys Secures CE Mark Approval for Felix™ System, Marking Commercial Inflection Point and Activating Global Growth Strategy

HIGHLIGHTS

- CE Mark approval achieved for the Felix™ System under EU MDR, unlocking full commercial deployment across Europe and other CE-recognised international markets.
- Immediate Access to ~A\$50+ million (€29+ million) Felix™ Addressable Market
- Binding, multi-year commercial agreements now activated, including:
 - a five-year European commercial agreement with CFA Italia valued at a minimum of ~A\$925,000, and
 - a five-year exclusive Middle East & North Africa (MENA) agreement with International Technical Legacy (ITL) with minimum contracted purchases of A\$390,000.
- Early cartridge orders already placed ahead of contractual triggers, providing tangible evidence of clinic-level demand.
- Company-led partners' preparation see clinics ready for immediate utilisation, with business development capability rapidly expanding to support scale-up across Europe and the Middle East
- Indian CDSCO and Australian TGA regulatory pathways to now progress under CE Mark mutual recognition, expected in July and April 2026 respectively.

Memphasys Limited (ASX: MEM) ("Memphasys" or the "Company") is pleased to announce that it has been granted CE (Conformité Européenne) Mark approval for its Felix™ automated sperm selection system.

The CE Mark confirms that Felix™ complies with the European Union Medical Device Regulation (EU MDR 2017/745), enabling commercial sale and clinical use across the European Economic Area (EEA) and other jurisdictions, such as Qatar, that recognise CE certification.

This approval represents a defining milestone for Memphasys - transforming Felix™ from a clinically validated technology into a globally deployable commercial product and marking the Company's continued transition into a revenue-scaling phase.

Immediate Access to ~€29+ million Addressable Market

Europe represents a substantial near-term market, with approximately 1.1 million assisted reproductive technology (ART) cycles performed annually across 1,382 clinics (2021 data)¹. Focusing solely on the ~418,000 ICSI cycles, where Felix™ delivers its greatest clinical and commercial advantage, this represents

¹ Refer <https://www.focusonreproduction.eu/press-releases/ivf-and-iui-treatment-cycles-increase-across-europe-along-with-stable-pregnancy-rates>

For personal use only

a Total Addressable Market of approximately €29+ million pa (+A\$50 million), based on an assumed €70 per-cycle utilisation.

At the clinic level, target IVF centres are expected to generate approximately A\$100,000 to A\$300,000 pa in annual recurring revenue, highlighting the attractive unit economics and scalability of the Felix™ platform.

CE Mark approval enables immediate commercial rollout, with clinics now positioned to adopt Felix™ into routine clinical practice.

Commenting on the milestone, **Lindley Edwards, Non-Executive Chairperson of Memphasys**, said:

“Felix™ has benefited from strong technical and scientific validation for many years. What we are now seeing is clear commercial validation emerging across a range of markets. Clinics are placing orders, partners are committing volumes, and demand is coming through independently in Europe, the Middle East, Japan and India.

This CE Mark approval is the moment where those foundations convert into scale. It reflects the Board’s focus on disciplined execution - aligning clinical proof, regulatory clearance and direct commercial engagement so Felix™ can now grow as a global product.”

During FY2026, Memphasys has executed a deliberate highly focussed strategy focused on:

- A go-direct sales strategy with embedded in-market commercial partner capability, enabling direct clinic engagement and rapid execution
- Secured volume-backed, multi-year commercial agreements, supporting recurring and scalable revenue
- Completed a gold-standard clinical trial, underpinning adoption by leading IVF clinics
- Progressed key regulatory approvals in parallel, accelerating access to regulated markets
- CE Mark approval achieved, activating existing contracts, unlocking revenue pathways and enabling global expansion

Existing Commercial Agreements Now Activated

With months of extensive in-market operational preparation completed, CE Mark approval has unlocked immediate commercial execution, activating multiple previously announced binding agreements and establishing Memphasys’ first contracted international revenue base for Felix™.

1. Europe – Italy (CFA Italia)²

- Five-year commercial supply agreement
- **Minimum contracted volume:** 7,500 Felix™ cartridges
- **Minimum contract value:** €525,000 (~A\$925,000)
- Initial cartridge orders already placed ahead of contractual obligation

This agreement provides Memphasys with its first commercial foothold in mainland Europe and a scalable entry point into one of the world’s largest IVF markets through established clinic networks.

² Refer ASX announcement dated 22 December 2025

2. Middle East & North Africa – ITL Agreement³

- Five-year exclusive commercial agreement
- Territory covering **15 MENA countries plus Turkey**
- **Minimum contracted cartridge purchases: A\$390,000**
- Early cartridge orders already placed ahead of contractual trigger

The ITL agreement provides immediate access to a large, established IVF clinic footprint across the Middle East and North Africa, with significant potential to scale recurring cartridge demand as utilisation expands.

What Felix™ Is - and Why Clinics Are Adopting It

The Felix™ System is a next-generation medical device designed to improve sperm preparation for assisted reproductive technology.

Felix™ replaces traditional centrifugation-based methods with a standardised, automated process that uses electrophoresis and size-exclusion membranes to rapidly and gently isolate high-quality sperm cells.

Key attributes include:

- automated processing in approximately six minutes,
- improved laboratory efficiency and throughput,
- consistent, user-independent performance,
- reduced mechanical stress on sperm,
- improved clinical outcomes especially against Density Gradient Centrifugation (DGC),
- A reduction in the potential risk of error due to the integrated approach using only one disposable cartridge.

For IVF clinics, Felix™ offers a rare combination of clinical performance, operational efficiency and scalability.

India and Australia - Next Growth Phases

With CE Mark approval secured:

- **India:** The regulatory process will now formally progress, supporting activation of existing commercial arrangements in one of the world's fastest-growing IVF markets. Central Drugs Standard Control Organisation (CDSCO) is expected to take approx. 6 months to complete, after which time sales under the agreement with Andrology Center group company Andro Diagnostics, Coimbatore⁴ can commence.
- **Australia:** The ARTG inclusion process will commence leveraging CE Mark conformity with Therapeutic Goods Administration (TGA) approval expected by April 2026.

Both markets represent meaningful medium-term growth opportunities for Felix™.

³ Refer ASX announcements dated 8 & 18 September 2025

⁴ Refer ASX announcement dated 28 October 2025

Outlook

CE Mark approval marks the point at which Felix™ moves from promise to execution. With go-direct sales strategy executed, binding contracts activated, clinics ready to commence utilisation, improving unit economics and expanding in-market capability, Memphasys enters FY2026 positioned for accelerating commercial execution, margin expansion and sustainable recurring revenue growth.

Authorised by the Board of Memphasys Limited.

Ends

For further information, please contact:

David Tasker
Managing Director
Chapter One Advisors
Tel: +61 433 112 936
E: dtasker@chapteroneadvisors.com.au

About Memphasys

Memphasys Limited (ASX: MEM) is an Australian-based reproductive biotechnology company commercialising the Felix™ System, a patented bio separation technology that isolates the most viable sperm cells for human assisted reproduction.

By combining electrophoresis and size-exclusion membranes, Felix™ delivers a fast, gentle and standardised sperm selection process that enhances sperm quality and reduces laboratory time. The system replaces traditional centrifugation, which can cause cellular stress and DNA damage, offering clinicians a superior, repeatable alternative.

Memphasys' commercial strategy focuses on building contracted sales through direct and distribution-led channels, scaling production to improve margins, and establishing Felix™ as a new global standard in sperm preparation for ART procedures.

Website: www.memphasys.com

The Felix™ System is a registered trademark of Memphasys Limited. All rights reserved.