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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 a 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

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

Exisiting 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 Agreement[3]

- 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, Coimbatore[4] 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.

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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

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