

ASX Release
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ASX Code: MEM

Memphasys Achieves ISO 13485 Compliance Draft Quality Management System Certification issued

Key Points

- The draft ISO 13485 certificate has been issued.
- BSI, an international regulatory accreditation body, undertook the audit and final certification is being processed by the auditor's UK head office.
- ISO 13485 is the international standard that demonstrates a company's ability, through its quality management system ("QMS"), to provide medical devices and related services to meet customer and applicable regulatory requirements.
- ISO 13485 assists with selling medical devices in high regulatory markets such as Australia, Europe and China, and is an important accreditation for product adoption by end users in other markets.

Australian-based reproductive biotechnology company Memphasys Limited (ASX: MEM) ("Memphasys" or "the Company") is pleased to advise it has achieved ISO 13485 (QMS) compliance (certification number MD 703870) for the company's QMS.

ISO 13485 is the international standard for medical industry QMS systems, established by the International Organisation for Standardisation (ISO). Having ISO 13485 certifies that the Company meets the comprehensive medical device requirements set out in this standard.

The Memphasys QMS is implemented using the international, specialist "Greenlight Guru" software system. The QMS system enables Memphasys to manage product development, production, product distribution and sales, and post market product surveillance and support.

Commenting on the ISO 13485 compliance, Memphasys Executive Chairman Alison Coutts said:

"I am pleased that Memphasys has received this initial certification and that final certification is being processed. The ISO 13485 certification is extremely important as it provides international accreditation for our QMS. Its achievement not only supports product regulatory filings in high regulatory markets but will also assist with market access in low regulatory markets."

This announcement has been approved for release by the board of Memphasys Limited.

ENDS

For further information please contact:



Alison Coutts
Executive Chairman
Memphasys Limited
T: +61 2 8415 7300
E: alison.coutts@memphasys.com

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

About Memphasys:

Memphasys Limited (**ASX: MEM**) specialises in biological separations and reproductive biotechnology for high value commercial applications.

Reproductive biotechnology products in development include medical devices, in vitro diagnostics, and new proprietary media.

The Company's patented bio-separation technology, utilised by the Company's most advanced product, the Felix™ device, combines electrophoresis with proprietary size exclusion membranes to separate the most viable sperm cells for human artificial reproduction.

Website: www.memphasys.com