

Singular Health Group Ltd: SHG

ASX Announcement

20th February 2024

Singular Health Retains ISO13485:2016 Certification at New Facility

- Successful site verification and surveillance audit results in renewal of ISO13485:2016 and verification of Bibra Lake address as Medical Device Establishment.
- Continued participation in Medical Device Single Audit Program (MDSAP) and retention of ISO13485:2016 certification demonstrates ongoing adherence to best-in-class global standards for quality assurance and medical device development.

20 February 2024 – Medical technology company Singular Health Group Ltd (ASX: SHG) (“Singular Health”, or “the Company”) is pleased to advise it has been notified of the successful re-issuance of a ISO13484:2016 Certificate for the design and development of Software-as-a-Medical Device for diagnostic review, and of its continued compliance with regulatory and quality requirements of Health Canada, the Therapeutic Goods Administration (Australia), and Food and Drug Agency through the Medical Device Single Audit Program (MDSAP).

The recent relocation of Singular Health’s software development activities from the previous Subiaco-based office to the consolidated Bibra Lake premises required notification to the US Food and Drug Administration (FDA), British Standards Institute (BSI), Singular’s notified body, and additional quality and regulatory updates due to its status as a Medical Device Establishment. An onsite site verification audit at the Bibra Lake premises was combined with the required annual surveillance audit and submitted for panel review with the Company’s external, independent auditing body, BSI.

ISO13485 is the primary standard for medical device development and manufacture and has been globally adopted by almost all leading medical device regulatory bodies as a prerequisite for the registration of Class II and higher medical devices.

Commenting on the retention of the ISO13485 Certification, Singular Health’s Chief Executive Officer and Managing Director, Denning Chong, said:

“The successful passing of our annual surveillance audit by BSI, an independent auditing body, demonstrates our strong commitment to quality and risk management in our development of diagnostic medical software and enables us to seek further regulatory approvals on a global scale.”

This announcement is authorised for release by the Board of Directors of the Company.

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For further information contact

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About Singular Health:

Singular Health Group Limited (ASX: SHG) is a medical technology company utilising advanced technologies to develop patient-specific solutions.

Singular Health’s 3Dicom software solutions empower patients and practitioners to better visualise, communicate, and understand medical imaging data. 3Dicom MD® is cleared for diagnostic use in the United States.

Singular 3DP, a wholly owned subsidiary of Singular Health, uses advanced manufacturing including 3D printing and post-processing to manufacture TGA-approved patient-specific medical devices.

To learn more, visit: <https://www.singular.health> and <https://investors.singular.health/>