4DMedical secures regulatory approval for CT:VQ™ in Canada

15 December 2025

Highlights

- 4DMedical receives Canadian regulatory approval for CT:VQ™, expanding access to breakthrough non-contrast VQ imaging
- Strengthens Philips partnership for distribution of CT:VQ™ across North America
- Regulatory approval enables immediate commercial deployment through Philips' established distribution network
- Canada represents a significant addressable market with population of over 40 million served by approximately 560 CT scanners

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Melbourne, Australia, 15 December 2025: 4DMedical Limited (ASX: 4DX, "4DMedical" or the "Company") a global leader in respiratory imaging technology, today announces Canadian regulatory approval for CT:VQ™, the world's first and only non-contrast, CT-based ventilation-perfusion imaging solution.

This approval marks a significant expansion of 4DMedical's presence in North America, enabling immediate commercial deployment of CT:VQ™ across Canada through the Company's strategic partnership with Philips.

Canadian regulatory approval unlocks major market opportunity

Health Canada has granted regulatory approval for CT:VQ™ as a Class 2 Medical Device under the Medical Devices Directorate.

Canada represents a substantial market opportunity for CT:VQ™. With a population exceeding 40 million and GDP of over US$2.1 trillion (ranked 10th globally), Canada's healthcare system includes approximately 560 CT scanners, predominantly hospital-based (94%). The Canadian market performs over 6.4 million CT examinations annually, with 12.7% related to respiratory imaging, representing over 800,000 potential CT:VQ™ procedures per annum.

Significantly, 70% of Canada's population resides below the 49th parallel, with 90% living within 160 km of the U.S. border. This geographic concentration positions the Canadian market within easy reach of 4DMedical's and Philips' U.S.-based commercial teams, enabling efficient market penetration and support.

Strengthens Philips partnership for North American distribution

The Canadian approval directly complements 4DMedical's strategic partnership with Philips, announced on 3 December 2025, which includes distribution rights for CT:VQ™ across both the United States and Canada. Under that agreement, Philips has committed to deploy dedicated sales and clinical specialists carrying North American CT:VQ™ sales targets.

With regulatory approval now secured in both markets, Philips can immediately activate its North American distribution infrastructure for CT:VQ™, leveraging its established commercial networks and customer relationships to drive rapid adoption across hospitals and imaging centres.

The future of lung health

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CT:VQ™ technological and clinical advantages

CT:VQ™ is the world's first technology capable of delivering quantitative ventilation-perfusion (VQ) data from routine non-contrast CT scans. The technology measures regional lung tissue motion and local density changes to generate comprehensive ventilation and perfusion maps without requiring radiotracers or contrast agents.

CT:VQ™ addresses several critical limitations of traditional nuclear VQ imaging. By eliminating radiotracers, the technology streamlines scheduling, improves patient access, and removes complex handling requirements and regulatory constraints. CT:VQ™ integrates seamlessly with existing CT protocols, requiring no additional infrastructure or specialised equipment, while delivering superior image resolution and precise quantification from a routine CT scan.

Critically, CT:VQ™ democratises access to advanced VQ imaging by leveraging the extensive installed base of CT scanners across healthcare systems. This broad accessibility extends advanced VQ imaging capabilities to rural and community healthcare facilities that may lack nuclear medicine infrastructure, offering improved diagnostic precision and patient outcomes.

Expanding addressable market across North America

Nuclear VQ scans represent a substantial global market. In the United States alone, over one million nuclear VQ scans are performed annually at an average reimbursement rate of approximately US$1,150 per scan, representing an addressable market exceeding US$1.1 billion annually in the U.S. and an estimated US$2.6 billion globally.

Given the clinical and logistical advantages of CT:VQ™ over traditional nuclear VQ imaging modalities, 4DMedical expects CT:VQ™ to rapidly capture significant market share and, over time, displace 100% of nuclear VQ scans. Management also anticipates that the introduction of CT:VQ™ into the market will drive long-term growth in demand for ventilation-perfusion scans beyond traditional nuclear VQ indications.

4DMedical MD/CEO and Founder Andreas Fouras said:

Securing Canadian regulatory approval for CT:VQ™ represents a major commercial milestone and is a key step in positioning CT:VQ™ as the standard of care for VQ imaging across North America.

This approval, combined with our recent Philips partnership, positions 4DMedical to execute an aggressive North American rollout strategy. With regulatory approvals now secured across both the U.S. and Canada, and with Philips' world-class commercial infrastructure committed to driving CT:VQ™ adoption, we have all the pieces in place to rapidly scale revenue and deliver transformative respiratory diagnostics to patients across the continent.

The market momentum we're seeing is extraordinary. Following exceptional clinician engagement at RSNA and commercial launches at leading academic medical centres like Stanford and University of Miami, we're now positioned to accelerate adoption across a much broader network of hospitals and imaging centres throughout North America.

–ENDS–

Authorised by the 4DMedical Board of Directors.

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About 4DMedical

4DMedical Limited (ASX:4DX) is a global medical technology company revolutionising respiratory care with advanced imaging and artificial intelligence. Its patented **XV Technology®** transforms standard scans into rich, functional insights that allow physicians to detect, diagnose, and monitor lung disease earlier and with greater precision.

4DMedical's expanding software portfolio includes the FDA-cleared **XV Lung Ventilation Analysis Software (XV LVAS®)**, **CT LVAS™**, and the ground-breaking **CT:VQ™** solution designed to set new benchmarks in cardiothoracic imaging by combining ventilation and perfusion analysis.

Delivered seamlessly through a Software-as-a-Service (SaaS) model, 4DMedical's solutions integrate into existing hospital infrastructure, enhancing physician productivity and enabling more personalised patient care. With the addition of advanced AI capabilities from its 2023 acquisition of **Imbio**, 4DMedical continues to push the boundaries of medical imaging to redefine how respiratory disease is understood and treated worldwide.

Learn more at www.4dmedical.com