

Nova Eye Medical Receives EU MDR Certification

Highlights

- **EU MDR certification achieved for Nova Eye's iTrack™ product portfolio.**
- **Key regulatory milestone that demonstrates the robustness of the Company's quality and regulatory systems.**
- **Enables Nova Eye to advance its commercial initiatives globally.**

Nova Eye Medical Limited (ASX: EYE) (**Nova Eye or the Company**), a medical technology company committed to advanced ophthalmic treatment technologies and devices, is pleased to announce that it has received European Union (EU) Medical Device Regulation (**EU MDR 2017/745**) certification from Intertek Medical Notified Body AB.

Referred to as the EU Quality Management System Certificate (Annex IX), the EU MDR certification enables CE marking of Nova Eye's iTrack™ products.

The EU MDR is the regulatory framework governing medical devices across the European Economic Area (EEA) and replaces the former European Medical Devices Directive (EU MDD). The regulation offers a significantly enhanced framework governing risk management, clinical evidence, traceability, transparency, and lifecycle product oversight.

This is an important milestone for the Company's global business. It directly supports the continued commercial supply of our iTrack™ products throughout Europe and bolsters Nova Eye's global regulatory standing in supporting future product registrations and commercial expansion initiatives.

During the 12 months ended 31 December 2025, the Company generated total sales in Europe of US\$3.1 million (A\$4.7 million growing at ~12% y.o.y.), representing 15% of total revenues of US\$21 million (A\$32 million growing at 24% y.o.y.).

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Authorised for lodgement by the Board of Directors of Nova Eye Medical Limited.

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ABOUT NOVA EYE MEDICAL

Nova Eye Medical Limited is a medical technology company that develops, manufactures and sells a portfolio of proprietary ophthalmic treatment technologies and devices. Used by eye surgeons globally, these technologies include iTrack™ Advance, a minimally invasive consumable glaucoma surgical device that restores the eye's natural outflow pathway to lower pressure inside the eye and to eliminate patient reliance on anti-glaucoma medications for mild-moderate glaucoma. The Molteno3® glaucoma drainage device platform is designed to enhance surgical utility and optimize clinical outcomes for long-term IOP control in cases of severe glaucoma. It also offers the benefit of a simplified and faster surgical procedure. With its sales headquarters based in Fremont, California, Nova Eye Medical is supported by a global network of distribution partners. Manufacturing facilities are located in Fremont, California and Dunedin, New Zealand.

For additional information about Nova Eye Medical and its technologies, please visit: www.nova-eye.com