



JOINT PRESS RELEASE

CLEARLAB CONTACT LENSES AND LENS CARE PRODUCTS RECEIVE COMBINED MDSAP, ISO13485 AND EU MDR CERTIFICATION FROM DNV

Parallel audit streamlines certification and speeds up access to global markets

21 January 2026, Singapore – DNV, the independent global assurance and risk management provider, has certified contact lenses and multi-purpose lens care solutions from Clearlab in accordance with the Medical Device Single Audit Program (MDSAP), ISO13485 Quality Management System for Medical Devices and the European Union Medical Device Regulation (MDR) 2017/745.

The certifications were achieved through a parallel audit, enabling Clearlab to be assessed against multiple regulatory frameworks simultaneously. This integrated approach significantly reduced audit time and complexity, supporting a faster and more efficient certification process.

Medical devices are subject to strict regulatory requirements to demonstrate their safety and quality before entering the market. As each market applies its own regulatory framework, multi-market certification can be complex and time-consuming. To address this challenge, regulatory authorities in Australia, Brazil, Canada, Japan and the United States developed the MDSAP based on the ISO13485 standard. Under the MDSAP, a single regulatory audit can provide access to up to these five markets, as well as those in affiliate member nations. Similarly, compliance with the EU MDR enables access to the entire EU and EEA markets.

As an MDSAP Auditing Organization and a designated Notified Body under EU regulations, DNV is authorized to conduct audits for both certification schemes, enabling manufacturers to efficiently access major global markets.

To support Clearlab in bringing its innovative high-quality contact lenses and multi-purpose lens care solutions to a wider customer base more quickly, DNV assessed the products against the MDSAP,

ISO13pp485 and MDR requirements in a parallel audit. This integrated approach minimizes duplication and audit burden for manufacturers while providing greater flexibility to optimize go-to-market timelines.

“By meeting the requirements of MDSAP, ISO 13485, and MDR through a single audit stream, Clearlab strengthens its compliance posture and accelerates access to key global markets, including Europe, Asia Pacific, and other regulated regions. The certifications confirm that Clearlab’s contact lenses and lens care products meet internationally recognized standards for quality management, safety, and regulatory compliance. The successful outcome highlights the value of coordinated audits in supporting medical device manufacturers as they navigate increasingly complex regulatory landscapes, while maintaining high standards of product quality and patient safety” said Hae Kyeong Park, Managing Director, Clearlab.

“One of the biggest challenges facing manufacturers of innovative medical devices is the time it takes to get products certified for all their target markets and the impact that has on global rollout plans. Parallel multi-standard audits can make a real difference. We are pleased to have supported Clearlab in bringing their contact lens products to a wider market faster thanks to the close communication and tailored audit planning made possible by our local team,” added Cecilie Gudesen Torp, Global Director Medical Services, DNV.

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