PRESS INFORMATION

Olympus Announces CE Approval for Three Cloud-based AI Medical Devices and Announces Plans for Launch of AI-Powered Endoscopy Ecosystem in 2025

Hamburg, October 14, 2024 – Olympus Europa SE & Co. KG (Olympus), a global MedTech company, today announced that its group company, Odin Medical Ltd. (Odin Vision), has received approval for its innovative cloud-AI (artificial intelligence) endoscopy medical devices – CADDIE, CADU, and SMARTIBD as CE-marked medical devices in Europe under the Medical Device Regulation (MDR). This approval marks a significant milestone in Olympus' efforts to enhance clinical outcomes and operational efficiency in endoscopy.

Leveraging its position as a market leader in capital equipment for endoscopy, Olympus aims to enhance its diverse hardware portfolio by cloud-based AI capabilities. The company's vision of an innovative Intelligent Endoscopy Ecosystem connects hardware, software, services, and data to address the pressing challenges in healthcare, particularly in the endoscopy space. This vision is driven by the overarching aim to harness the power of data and AI to strengthen clinical decision-making and improve operational efficiencies.

By obtaining regulatory approval under MDR for Odin Vision's cloud-based AI medical devices[1], Olympus takes the first significant milestone in the effort to launch an Intelligent Endoscopy Ecosystem.

CADDIE: This AI-driven device assists gastroenterologists in detecting and characterizing suspected colorectal polyps and potential early signs of colorectal cancer. With both cloud-based computer-aided detection (CADe) and diagnosis (CADx) functions, it aids clinicians in analyzing the tissue's visual characteristics.

CADU: Another cloud-based AI solution, CADU is intended to aid in analyzing dysplasia in patients with Barrett's Esophagus during endoscopy procedures, analyzing data in real-time for endoscopists.

SMARTIBD: This AI solution is designed to aid clinicians in analyzing ulcerative colitis during colonoscopy procedures. It processes colonoscopy video frames and provides real-time insights to help characterize tissue.

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[1]For detailed information regarding instructions for use, indications, contraindications, warnings, and precautions, please consult the device manual.

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"We are excited about this significant advancement in our technology innovation and patient care with our vision of the Intelligent Endoscopy Ecosystem," said Miquel-Àngel García, Global Head of Endoscopy Solutions Ecosystem at Olympus. "These solutions represent a transformative shift in endoscopy, where technology is delivered not only through new equipment but also through data, artificial intelligence, and continuous innovation that empower healthcare professionals and can ultimately improve patient outcomes."

"The regulatory approvals for our three AI software medical devices under MDR demonstrate our commitment to quality and patient safety," added Dr. Karsten Klose, Global Head of the Digital R&D Unit at Olympus. "By integrating AI and cloud-based technology, we are paving the way for a new era in endoscopy, where medical professionals can deliver the best possible care with unprecedented reliability and efficiency."

Olympus is currently piloting cloud-AI endoscopy systems in selected European hospitals aiming to evaluate the solutions in real-world clinical settings, ensuring they address the unmet needs of healthcare providers and patients. Following successful pilot programs, Olympus plans to commercialize these solutions in the EMEA (Europe, Middle East, and Africa) region in selected countries starting with the commercial launch of these three cloud-based AI software medical devices in Q1 2025.

Olympus is showcasing its latest solutions during pre-scheduled sessions at the **UEGW** Congress in Vienna from October 13 to 15, 2024.

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About Olympus

At Olympus, we are committed to our Purpose of making people's lives healthier, safer, and more fulfilling. As a global medical technology company, we partner with healthcare professionals to provide best-in-class solutions and services for early detection, diagnosis, and minimally invasive treatment, aiming to improve patient outcomes by elevating the standard of care in targeted disease states.

For more than 100 years, Olympus has pursued the goal of contributing to society by producing products designed with the purpose of delivering optimal outcomes for its customers around the world.

For more information, visit **www.olympus-europa.com** and follow our LinkedIn account: **linkedin.com/company/olympusmedemea/**.

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