Cosmo Receives CE Certification for ColonPRO EU – The most Advanced AI Software Platform for Colonoscopy in Europe

Dublin, Ireland – November 3, 2025: Cosmo Pharmaceuticals N.V. (SIX: COPN), a global leader in AI-powered healthcare and specialty pharma, today announced that ColonPRO EU, the Company's next-generation artificial intelligence software for colonoscopy, has received CE certification. Following FDA clearance in the United States, this certification brings to Europe the most advanced AI-assisted colonoscopy platform ever developed. The system has already been used to support more than four million procedures worldwide.

ColonPRO EU integrates four complementary AI modules that work together to support physicians through every step of colonoscopy – from detection to diagnosis, measurement, and quality assessment:

- Real-time Polyp Detection (CADe): Validated in multiple international trials, including COLO-DETECT (The Lancet Gastroenterology & Hepatology, 2024), showing an 8.3 percentage-point improvement in adenoma detection rate versus standard colonoscopy. The latest version further increases specificity, reducing false positives by 9%.
- Real-time Polyp Characterization (CADx): Proven in the PRACTICE randomized controlled trial (The Lancet Gastroenterology & Hepatology, 2025) to safely support "diagnose-and-leave" strategies for diminutive polyps, reducing unnecessary resections without compromising safety.
- Real-time Polyp Sizing (CADs): Introduced for the first time in ColonPRO EU, validated in the METER study (Endoscopy, 2025), achieving 85.8% accuracy in size classification and 90.8% correctness in surveillance-interval assignment per ESGE guidelines.
- Procedure Highlights (CAQ): Newly added to automatically capture inspection times, bowel-prep scores, and caecal-intubation rates — providing objective quality metrics that allow endoscopy units to monitor performance and continuously improve outcomes.

Together, these modules form a seamlessly integrated and clinically proven AI suite that enhances every phase of colonoscopy, combining precision, efficiency, and real-time quality assurance.

Powered by twelve concurrent neural networks and operating on Cosmo's proprietary NVIDIA IGX-based hardware platform, ColonPRO EU runs side-by-side with other AI Access software modules, forming the core of the Cosmo Live AI ecosystem.

"With ColonPRO EU, we are setting a new benchmark for AI in endoscopy," **said Nhan Ngo Dinh, President of the MedTech AI Division at Cosmo**. *"This suite combines detection, characterization, sizing, and quality assessment in one intelligent system. It embodies our vision: an adaptive AI assistant that empowers physicians and helps hospitals continuously elevate the standard of care."*

Since the first GI Genius™ launch in 2019, Cosmo's AI technology has supported over four million patients globally. The CE certification of ColonPRO EU reinforces the Company's leadership in AI-enabled endoscopy, combining world-class clinical evidence, advanced engineering, and a relentless commitment to innovation in colorectal-cancer prevention.

About Cosmo

Cosmo is a life sciences company focused on MedTech AI, dermatology, gastrointestinal diseases, and contract development and manufacturing (CDMO). We design, develop, and manufacture advanced solutions that address critical medical needs and raise the standard of care. Our technologies are trusted by leading global pharmaceutical and MedTech companies and reach patients and healthcare providers around the world. Guided by our purpose - Building Health Confidence - our mission is to empower patients, healthcare professionals, and partners by innovating at the intersection of science and technology. Founded in 1997, Cosmo is headquartered in Dublin, Ireland, with offices in San Diego (USA), and in Lainate, Rome, and Catania (Italy). For more information, visit www.cosmohealthconfidence.com

Financial calendar

Jefferies Global Healthcare Conference, London, United Kingdom	November 17-20, 2025
Berenberg European Conference, Windsor, United Kingdom	December 1-4, 2025
ODDO BHF Forum, Lyon, France	January 8-9, 2026

For further information, please contact:
investor.relations@cosmohc.com