

# Bracco Imaging Achieves New Global Milestone with ANVISA Clearance of AiMIFY™ in Brazil

Regulatory Approval Expands Access to AI-Powered Diagnostics Across Latin America, Following FDA and CE Mark Clearances

20 NOVEMBER 2025, MILAN – Bracco Imaging S.p.A., a global leader in diagnostic imaging, and Subtle Medical, Inc., a pioneering innovator in artificial intelligence (AI)-powered medical imaging software, announced today that AiMIFY™, their jointly developed AI-powered software for Magnetic Resonance Imaging (MRI) of the brain, has received ANVISA (Agência Nacional de Vigilância Sanitária) approval in Brazil. This milestone marks the latest achievement in Bracco's global expansion of next generation imaging solutions, following previous clearances by the U.S. Food and Drug Administration (FDA) and CE (Conformité Européenne) Marking in Europe.

With ANVISA approval, Bracco is now working to make AiMIFY™ available to imaging providers across Brazil, enabling broader access to advanced diagnostic innovation in one of Latin America's most strategically important healthcare markets.

AiMIFY™ leverages advanced AI technology to amplify the contrast enhancement of brain MRI scans after administration of a labelled dose of Gadolinium-Based Contrast Agents (GBCAs) up to twice the initial value.

This provides radiologists with improved contrast information - particularly aiding in the visualization of small and poorly enhanced lesions. AiMIFY™ has demonstrated consistent performance across a wide range of validation data, including diverse patient demographics, pathologies, lesion sizes, scanner vendors, MRI sequences, and acquisition orientations.

*"We are proud to bring AiMIFY™ to Brazil following ANVISA approval, building on our momentum as a global leader in diagnostic imaging innovation," said Sascha Daeuber, Global Radiology Platform Leader at Bracco Imaging. "This milestone reflects our continued commitment to advancing precision diagnostics by enabling radiologists to gain clearer, more confident insights from brain MRI. AiMIFY™ represents an important step in expanding access to innovative imaging solutions across Latin America."*

*"MRI is the preferred Imaging Modality in Latin America and Bracco has built the most comprehensive portfolio in this field, covering innovative contrast agents, injectors and IT solutions," said Tommaso Montemurno, General Manager for Latin America at Bracco Imaging. "The ANVISA approval of AiMIFY™ reinforces our regional commitment to support radiologists with innovative tools that help elevate diagnostic standards."*

*"We are excited to see AiMIFY™ boost the impact of MRI imaging in Brazil," said Josh Gurewitz, Chief Commercial Officer at Subtle Medical. "This is a key step in our mission to improve global access to advanced medical imaging. With the combined power of AiMIFY™ and SubtleHD™, imaging providers in Brazil can unlock greater diagnostic precision and operational efficiency without costly hardware upgrades."*

AiMIFY™ is manufactured for Bracco Imaging S.p.A. by Subtle Medical Inc. – Menlo Park, CA, USA 94025.

AiMIFY™ is a trademark of Bracco Imaging S.p.A.

For additional information about Bracco's products, and for full prescribing information, please visit <https://www.bracco.com/>.

#### About Bracco Imaging

Bracco Imaging is a global leader in diagnostic imaging, dedicated to improving people's lives by shaping the future of prevention and precision medicine. With a strong passion for innovation, the company develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging: contrast agents for X-ray, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI), as well microbubbles for Contrast Enhanced Ultrasound (CEUS), and Molecular Imaging through radioactive tracers and novel PET imaging agents, alongside specialized medical devices and related services.

The company is committed to advancing radiology by sharing knowledge to cultivate future thought leaders, linking today's practice with tomorrow's progress. Since 1927, Bracco Imaging has grown to more than 3,800 employees and now supports patients and radiology professionals in over 100 countries.

Discover Bracco Imaging at [www.bracco.com](http://www.bracco.com).

#### About Subtle Medical

Subtle Medical is a leading provider of AI-powered imaging solutions, optimizing scan efficiency and image quality across radiology. Recognized as a CB Insights GenAI 50 company and twice named among the CB Insights Top AI 100 and Digital Health 150, Subtle Medical is dedicated to innovation in medical imaging. Deployed globally across 900+ scanners, our solutions help imaging centers and hospitals improve workflow efficiency, enhance scanner longevity, and elevate patient outcomes. Learn more and request a demo at [www.subtlemedical.com](http://www.subtlemedical.com).

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