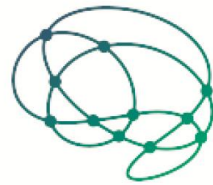


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Bracco Imaging and Subtle Medical Announce CE Mark of AiMIFY™ Software for Enhanced MRI in Europe

16TH JUNE 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 image acquisition, announced today that AiMIFY™, their jointly developed AI-powered software for magnetic resonance imaging (MRI) of the brain, has received the CE (Conformité Européenne) Mark under the European Medical Device Regulation (MDR). This regulatory milestone confirms the compliance of AiMIFY™ with EU safety, health, and environmental protection standards.

AiMIFY™ leverages advanced AI technology to amplify the contrast enhancement of brain MRI scans — up to twice the level typically achieved with a labeled dose of gadolinium-based contrast agents (GBCAs). This provides radiologists with improved contrast information - particularly aiding in the visualization of small and poorly enhanced lesions, which can be critical for the early detection and assessment of certain conditions. AiMIFY™ has



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demonstrated consistent efficacy 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 extend our successful partnership with Subtle Medical into the European market," said Sascha Daeuber, Radiology Platform Leader at Bracco Imaging. "From the beginning, Subtle has proven to be an agile and visionary partner—our joint announcement of FDA clearance last year underscored that strength. With the CE Mark for AiMIFY, we're taking the next step in our shared mission to deliver innovative, AI-powered solutions that enhance diagnostic precision and support radiologists and patients worldwide."

"We're thrilled to see AiMIFY™ achieve CE Marking, a milestone that validates the strength of our collaboration with Bracco Imaging and the clinical value of this breakthrough technology," said Ajit Shankaranarayanan, PhD, Chief Product Officer at Subtle Medical. "AiMIFY™ represents a new frontier in AI-powered imaging—bringing enhanced clarity and confidence to brain MRI reads, without requiring changes to the standard of practice in contrast imaging. We're excited to expand access to this innovation across Europe and continue advancing precision diagnostics for patients and radiologists alike."

Bracco and Subtle Medical will now begin preparation activities to enable commercial availability of AiMIFY™ in key European markets. These efforts will continue throughout 2025, with a phased commercial rollout expected between late 2025 and early 2026.

On June 17th, *Applied Radiology* will spotlight AiMIFY™ in a [webinar](#) featuring expert insights from both Bracco and Subtle Medical. The session will be recorded and available on demand.

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.

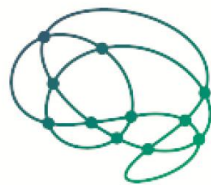
For additional information about Bracco's products, and for full prescribing information, please visit <https://www.bracco.com/>.

About Bracco Imaging

Bracco Imaging S.p.A. ("Bracco Imaging"), part of the Bracco Group, is an innovative world leader delivering end-to-end products and solutions through its comprehensive portfolio across diagnostic imaging modalities. Headquartered in Milan, Italy, Bracco Imaging's purpose is to improve people's lives by shaping the future of prevention and precision diagnostic imaging. The Bracco Imaging portfolio includes products and solutions for all key diagnostic imaging modalities: X-ray imaging, magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents. Bracco Imaging has 3,800 employees and operates in more than 100 markets globally. Bracco Imaging has a well skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. Discover Bracco at <https://www.bracco.com/>.

About Subtle Medical

Subtle Medical is a global leader in AI-powered technology for faster, safer, and smarter medical imaging. The company's cutting-edge solutions for faster imaging optimize radiology workflows, improving productivity and patient experience. Subtle Medical has been recognized as a CB Insights GenAI 50 company and has been named to the CB Insights Top AI 100 and Digital Health 150 lists multiple times. By harnessing the power of artificial intelligence, Subtle Medical is transforming the future of healthcare. For more information, please visit subtlemedical.com or email sales@subtlemedical.com.



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Media Contacts:

Bracco Press Contact:

Carolina Bargoni

Bracco Imaging, Communications Director

Carolina.bargoni@bracco.com

+39 347 5397738

Subtle Medical

Anna Menyhart

Head of Global Marketing

anna@subtlemedical.com

+1 501-766-2662



Carolina Bargoni

Communications Director

Bracco Imaging S.p.A.

Bracco is an **international Group** active in over 100 countries worldwide in the healthcare sector and a leader in **diagnostic imaging**. It has 3,700 employees and annual total consolidated revenues of around 1,8 billion euros, 88% of which from international sales. In the Research and Development area, the company invests approximately 10% of reference turnover in the imaging diagnostics and medical devices sectors and has a portfolio comprising over 2,600 patents.

Anna Menyhart

Head of Marketing

Subtle Medical Inc.

Subtle Medical is a global leader in AI-powered technology for faster, safer, and smarter medical imaging. The company's cutting-edge solutions for faster imaging optimize radiology workflows, improving productivity and patient experience. Subtle Medical has been recognized as a CB Insights GenAI 50 company and has been named to the CB Insights Top AI 100 and Digital Health 150 lists multiple times. By harnessing the power of artificial intelligence, Subtle Medical is transforming the future of healthcare.

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