



## **Acutus Medical Obtains MDR CE Mark of the AcQMap 3D Imaging and Mapping Catheter**

December 6, 2022

### **The flagship 3D mapping catheter from Acutus Medical has been certified under the new European Medical Device Regulations**

CARLSBAD, Calif., Dec. 06, 2022 (GLOBE NEWSWIRE) -- Acutus Medical, Inc. ("Acutus" or "the Company") (Nasdaq: AFIB), an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated, today announced receipt of a CE Mark issued under the European Union (EU) Medical Device Regulations (MDR) for its AcQMap 3D Imaging and Mapping Catheter, the world's only integrated high-resolution ultrasound imaging and non-contact mapping catheter.

The EU MDR was established to create a more robust legislative framework to better protect public health and patient safety. Acutus will file for EU MDR approval for the remaining products in the Company's portfolio to ensure compliance by the May of 2024 deadline. This will allow physicians to have long-term access to the Company's full portfolio of differentiated mapping, ablation, and EP accessory products.

"Obtaining our MDR CE Mark for AcQMap well before the transition date ensures that European patients and physicians will have continued access to our unique mapping technology offering individualized diagnosis and a personalized treatment plan for even the most complex arrhythmias," said Shibaji Shome, Vice President, Marketing at Acutus. "The MDR, with a significant focus on quality and safety, is well aligned with our commitment to improve patient care through innovative and high-quality medical devices. Importantly, this approval positions us well for further expansion and growth within the European markets."

In addition, the Company received MDR certification of its quality management system.

To learn more about Acutus Medical's complete portfolio of diagnostic, access and therapy products, please visit <https://acutusmedical.com>.

### **About Acutus Medical**

Acutus Medical is an arrhythmia management company focused on improving the way cardiac arrhythmias are diagnosed and treated. Acutus is committed to advancing the field of electrophysiology with a unique array of products and technologies which will enable more physicians to treat more patients more efficiently and effectively. Through internal product development, acquisitions and global partnerships, Acutus has established a global sales presence delivering a broad portfolio of highly differentiated electrophysiology products that provide its customers with a complete solution for catheter-based treatment of cardiac arrhythmias. Founded in 2011, Acutus is based in Carlsbad, California.

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