NEWS RELEASE

Inspire Medical Systems, Inc. Announces CE Mark Certification under the European Union's Medical Device Regulation for Inspire Therapy

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MINNEAPOLIS, July 19, 2024 (GLOBE NEWSWIRE) -- Inspire Medical Systems, Inc. (NYSE: INSP) (Inspire), a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea (OSA), today announced CE mark certification under the European Union's Medical Device Regulation (EU MDR 2017/745) for Inspire therapy.

"Inspire has a long history of compliance to the European Union's (EU) quality system and CE mark requirements, with uninterrupted CE mark approval since 2010," said Tim Herbert, Chairman and President of Inspire. "The Inspire team has worked diligently with our notified body in Europe to complete the review process, which included obtaining temporary approval through derogation authorization to continue to deliver Inspire product in several countries."

"In 2017 the European Parliament enacted a new regulatory framework (i.e., EU MDR 2017/745) for the certification of medical devices in the EU. As a result, the entire medical device industry must repeat the process for both design and quality system certification to the new, more stringent, requirements. The scale of this transition to a new regulatory framework has proven to be a challenge for medical device manufacturers and the notified bodies who certify them. Given that, Inspire is pleased to reach this critical milestone," said Andreas Henke, Executive Vice President, Managing Director Europe.

There are two changes to Inspire therapy that are now CE marked under the EU MDR, that were not previously certified under the Active Implantable Medical Device Directive (90/385/EEC). First, Inspire patients in the EU may

now undergo full-body MRI scans in the 1.5T MRI environment, provided the conditions specified in the Inspire MRI Guidelines Manual are met. Additionally, the current version of Inspire therapy's leads with silicone insulation are now CE marked in the EU.

About Inspire Medical Systems

Inspire is a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea. Inspire's proprietary Inspire therapy is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea.

For additional information about Inspire, please visit **www.inspiresleep.com**.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including, without limitation, those regarding our expectations to commercialize Inspire therapy in France. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including the factors identified under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the SEC, and as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at **www.sec.gov** and the Investors page of our website at **www.inspiresleep.com**. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

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