

PRESS RELEASE

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Senzimes TetraGraph system and new manufacturing facility certified against MDR

Pressrelease: Uppsala, on 6 December 2021. Senzime today announces that the company's products, quality system and manufacturing facility has been certified in accordance with the new European Medical Device Regulation (MDR).

Since May 2021, the European Medical Devices Regulation 2017/745 (MDR) is applicable in Europe, replacing the Medical Devices Directive (93/42/EEC) and introducing major changes to how medical device manufacturers obtain European market access. This transition involves an increased work effort compared to the MDD, since the MDR introduces a life-cycle approach for the CE Marking Compliance and introduces many new requirements.

Senzime early identified this as an important process, establishing a transition plan with focus on identifying the gaps between the current and new regulation. By meeting the quality, regulatory and domain specific requirements during the product life cycle through an effective and practical QMS and procedures, as well as well-adapted product testing and documentation, we maintain our competitive edge.

Pia Renaudin, CEO of Senzime, says: *"Safety and effectiveness are focus areas for us. A deep understanding and knowledge of continuously changing regulations and standards is imperative to our regulatory roadmap, and I am so proud to have our team deliver on this important milestone."*

Senzime was founded in Uppsala in 1999 and the company's shares are traded on Nasdaq Stockholm main market (ticker SEZI).

For further information, please contact:

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About Sensime

Senzime develops and markets CE- and FDA cleared patient monitoring systems driven by unique algorithms and sensors to closely monitor patients under anesthesia. TetraGraph is a system that digitally and continuously measures the degree of neuromuscular blockade in the patient. The goal is improved clinical precision and simplified management in healthcare. By preventing complications and enabling healthcare professionals to follow guidelines and drug recommendations, TetraGraph can contribute to shorten hospital stays and lower healthcare costs. The vision is a world without anesthesia related complications, where everyone wakes up safely after surgery. Sensime operates in growing markets that in Europe and the United States are valued in excess of SEK 15 billion. The company's shares are listed on Nasdaq Stockholm's main market (ticker SEZI) since June, 30 2021. www.senzime.com

Attachments

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