



## Senzime receives ISO 13485 certification

**Uppsala, June 12, 2017. Senzime AB (publ) has received ISO 13485 certification, which is an important milestone in the CE labeling process for the company's first monitoring products.**

Senzime has been certified according to ISO 13485 for its quality management system. ISO 13485 is the world's most widely used standard and quality management system for medical devices. The standard is harmonized with the EU regulations and an approved certificate demonstrates the company's ability to provide medical equipment that consistently meets customer requirements and current legal requirements.

The ISO certification demonstrates that Senzime meets the high standards of quality management for the development, manufacture, service and sale of patient monitoring products in the medical technology industry. ISO certification is required in the Medical Equipment Development Regulations and is an important step for CE marking of Senzime's first three monitoring products: OnZurf, CliniSenz and TetraGraph. CE mark approval for the three monitors is expected shortly.

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**TO THE EDITORS**

**About Senzime**

Senzime develops unique patient-oriented monitoring systems that make it possible to assess patients' biochemical and physiological processes before, during and after surgery. The portfolio of technologies includes bedside systems that enable automated and continuous monitoring of life-critical substances such as glucose and lactate in both blood and tissues, as well as systems to monitor patients' neuromuscular function perioperatively and in the intensive care medicine setting. The solutions are designed to ensure maximum patient benefit, reduce complications associated with surgery and anesthesia, and decrease health care costs. Senzime operates in growing markets that in Europe and the United States are valued in excess of SEK 10 billion. The company's shares are listed on Nasdaq First North (ticker SEZI). FNCA is Certified Adviser for Senzime. [www.senzime.com](http://www.senzime.com)