

# Nexstim

## Nexstim's Quality System and NBS 6 Receive MDR Certification in the EU

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Nexstim Plc (NXTMH:HEX) ("Nexstim" or "Company") has received certifications for its quality management system and NBS 6 product under MDR (Regulation (EU) 2017/745) in the European Union.

The EU quality management system certificate allows for Nexstim to start marketing and selling the NBS 6 system for the treatment of major depression and chronic neuropathic pain within the European Union. Nexstim announced on April 17, 2023, that it had launched NBS 6 in the United States for the treatment of Major Depressive Disorder (MDD).

The NBS 6 enables Nexstim's unique E-field navigated TMS technology to be used more easily than ever before. Part of this new product generation is an easy-to-use, software-guided application and a modular product design that allows for system capabilities to expand over time and be highly customized based on a customer's research or treatment interests.

Mikko Karvinen, CEO of Nexstim, comments:

*"The MDR conformity certification is an important step in the process of launching the NBS 6 and achieving one of our key strategic objectives for 2023. I am proud of the hard work our team has put into making the new software generation available in both the United States and the European Union in such a tight schedule. The EU quality management system certification will benefit us in the long term also by making any future product certification processes more efficient.*

*The NBS 6 received a great response as we attended and unveiled the product at the Clinical TMS Society Annual Meeting in Colorado Springs, United States earlier this month. We are expecting nothing less from the European market and are excited to continue the promotion work."*

Further information is available on the website [www.nexstim.com](http://www.nexstim.com), or by contacting:

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### About Nexstim Plc

Nexstim is a Finnish, globally operating growth-oriented medical technology company. Our mission is to enable personalized and effective diagnostics and therapies for challenging brain diseases and disorders.

Nexstim has developed a world-leading non-invasive brain stimulation technology for navigated transcranial magnetic stimulation (nTMS) with highly sophisticated 3D navigation providing accurate and personalized targeting of the TMS to the specific area of the brain.

Nexstim's Diagnostics Business focuses on commercialization of the Navigated Brain Stimulation (NBS) system. The NBS system is the only FDA cleared and CE marked navigated TMS system for pre-surgical mapping of the speech and motor cortices of the brain.

# Nexstim

Nexstim's Therapy Business markets and sells the Navigated Brain Therapy (NBT®) system, which is FDA cleared for marketing and commercial distribution for the treatment of major depressive disorder (MDD) in the United States. In Europe, the NBT® system is CE marked for the treatment of major depression and chronic neuropathic pain.

Nexstim shares are listed on Nasdaq First North Growth Market Finland.

For more information, please visit [www.nexstim.com](http://www.nexstim.com)