



## First step in the formal process towards certification

**As part of the process of getting market approval for selling and marketing medical technology equipment, NanoEcho has today taken the first step towards certification by having BSI (British Standard Institute) go through the company's processes. The aim is to evaluate how well the company complies with the current ISO standard, ISO-13485 Management system for medical technology, and identify any weaknesses in the company's quality management system.**

The certification is implemented to show that the company fulfils the regulatory requirements required to provide medical devices on the European market and is performed by an institute (notified body) approved by the authorities.

"We are facing a significant milestone. By initiating this process, we are stepping into the position of a medical technology company with the ability to develop medical technology products that meet the legal requirements. The certification is of great importance since it confirms that our company fully complies with the requirements and regulations required to sell and market technical products on the European market," says Linda Persson, CEO of NanoEcho.

NanoEcho works in accordance with the European Medical Device Regulations (MDR) and has for some time prepared the certification of the company's quality management system. The review of the company's processes, performed by our certification institute BSI, is the first step in the formal process. The goal is for the company to become ISO 13485 certified in 2024.

"The first step in the process went well, which shows that our way of working broadly with quality assurance has functioned well. The work has gone very smoothly thanks to the fact that many of us have previous experience of working with medical devices. Now we are looking forward to getting an ISO 13485 certification," says Kristina Hallström, quality manager of NanoEcho.

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**NANOECHO**  
next level diagnostics

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**NanoEcho** develops a new technology for clearer diagnostics of, in the first indication, rectal cancer. The imaging technology is based on a new medical approach where nanotechnology is used in combination with modern patented ultrasound technology. The images that are generated are intended to facilitate differentiation between healthy and diseased tissue and at the same time determine the location of the cancer tissue more precisely. The aim is to provide more precise, simple, and cost-effective diagnosis of cancers and other diseases. With clearer diagnostics, the company wants to assist treating physicians with better guidance for more personalised treatment. Both the quality of life of the patients and their chance of survival can improve after treatment, with reduced treatment costs. [www.nanoecho.se](http://www.nanoecho.se)