Press Release
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NanoEcho's quality management system, certified according to ISO 13485

After an extensive review process, NanoEcho's quality management system has today become ISO 13485 certified. This means that NanoEcho operates in accordance with the legal requirements for medtech companies, necessary for launching medical devices in the EU.

This certification is in practice a legal requirement for the company to be allowed to launch medical devices on the European market, according to the EU's medical technology regulations (MDR 2017/745).

> *"Today, completely according to plan, we have passed this significant milestone. We have carefully built a comprehensive quality management system, which has now undergone a thorough third-party review process. This proves that we work efficiently and structured as a medtech company, which forms a valuable basis for both our clinical phase and our upcoming market introduction"*, says Linda Persson, CEO at NanoEcho.

The certificate was issued by BSI Group The Netherlands B.V. after they carried out an extensive review of the company's work processes. BSI Group is authorised by the European Medicines Agency to ensure that the quality management system meets relevant laws and standards.

The certification facilitates the possibility of launching medical technology devices also in countries outside Europe.

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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 goal is to provide a more reliable diagnosis of, for example cancer diseases, that has the potential to contribute to cost-effectiveness in health care. www.nanoecho.se