

Lumito renews its quality certification, ISO 13485:2016

Lumito AB (publ) ("Lumito" or "the Company") today announces that the Company has had its quality certification renewed in accordance with the international standard ISO 13485:2016 – Medical devices – Quality management systems.

The audit was carried out by the independent assessment body BSI Group and confirms Lumito's clear focus on quality, safety, and regulatory compliance. The Company was certified according to ISO 13485:2016 in 2022 and has since undergone annual audits to ensure that the quality management system continuously meets the requirements of the standard.

"The certification is an important part of ensuring high quality in our work processes and demonstrates that our systematic quality efforts function in practice. It confirms our commitment to quality and safety at every stage", says Sanna Wallenborg, CEO of Lumito.

ISO 13485:2016 is an international standard that defines the requirements for quality management systems (QMS) for manufacturers of medical and diagnostic devices. The certification supports the Company by establishing documented and controlled processes for quality, risk management, and regulatory compliance. This is an important foundation for future work to bring a medical device intended for diagnostic use to the market.

For further information, please contact:

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About Lumito

Lumito specialises in medical technology and translational research in digital tissue imaging. Lumito offers a groundbreaking, highly sensitive imaging technique to locate and measure protein biomarkers in tissue samples using up-converting nanoparticles (UCNPs) through its patented research platform. The technology combines image data with precise biomarker detection, enabling images with higher contrast where irrelevant background information is filtered out. The technique can enhance the analysis of tissue samples by increasing objectivity, thereby contributing to research for more quantifiable diagnoses and optimised treatments. Lumito primarily focuses on drug development and digital pathology and is a spin-off from a research group at Lund University's Department of Atomic Physics and Laser Center. www.lumito.se/en/

The share is traded on NGM Nordic SME under the name LUMITO, and Mentor is Mangold Fondkommission.

Attachments

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