

Lumito has CE-marked its first product SCIZYS

Lumito has CE-marked its first product, SCIZYS. This is an important milestone for Lumito and means that sales for the histopathological research market can begin. SCIZYS S1 now fulfils all the relevant provisions of the EC Machinery Directive 2006/42/EC.

The internal work required to be able to CE mark the product after receiving the final report from the independent testing institute Nemko was completed on Thursday, and a "Declaration of Conformity" has now been signed. This declares that SCIZYS S1 now conforms with the following EU Directives: the Low Voltage Directive (2014/35/EU), the EMC Directive (2014/30/EU), and the RoHS Directive (2011/65/EU + 2015/863).

"It is with incredible pride and great joy that we have now, after a long period of hard work with the compliance testing, been confirmed that we meet all the requirements set to be able to CE mark a product aimed at the research market. This, together with the technical documentation, means that we finally were able to sign a Declaration of Conformity and thus CE mark Lumito's first product, SCIZYS. We are now ready to offer customers our solution and the company is fully entering a commercial phase", comments Lumito's CEO Mattias Lundin.

A CE mark for a product aimed at research is a self-declared CE mark and means that Lumito themselves signed a declaration of agreement, a so-called Declaration of Conformity.

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Lumito

Lumito specialises in medical technology for digital pathology. Through its proprietary and patented technology, Lumito aims to provide healthcare providers with a powerful tool to meet the demands for fast and safe tissue diagnostics in personalised healthcare. The technology enables higher-contrast images without irrelevant background information, making it easier for pathologists to find cancer indications. The technology, based on Up Converting NanoParticles (UCNP), has the potential to significantly improve the diagnosis of tissue samples through higher quality analyses and shortened analysis times. The method has several potential applications, but Lumito has focused primarily on digital pathology and first on a release of SCIZYS by Lumito for use in research laboratories. The company is a spin-off of a research group at the Department of Atomic Physics and Laser Centre. www.lumito.se/en

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

Image Attachments

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Attachments

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