

LIFE – SUCCESSFULLY ISO 13485 CERTIFIED

Bergen, Norway, January 9th, 2024: Today, Lifecare AS (LIFE), a clinical stage medical sensor company developing the next generation Continuous Glucose Monitor (CGM), can disclose that Lifecare Laboratory (Mainz, Germany) has received the official documentation for ISO 13485 certification.

Reference is made to Lifecare's stock exchange notification 27th of November 2022 when the ISO 13495 audit was conducted, and finalized, at Lifecare Laboratory. This progress is in accordance with the current list of communicated trigger events.

ISO 13485 is a Quality Management System specific to medical devices and covers the entire life cycle of a device, from design and development to production, installation, and servicing. Lifecare's ISO 13485 certification covers "Development services for manufacturers of medical devices such as CGM devices".

Lifecare's ultimate goal to enter the human market is product CE marking. Lifecare has now received ISO 9001 and ISO 13485 certification and thus signed off on two essential steps on the way to product CE mark.

- This was expected, but still incredibly gratifying to receive the confirmation that we are ISO 13485 certified. This is of course a very important step for the company and the organization. I can repeat that I am deeply impressed by how our QMS team in Bergen and Mainz have driven this process forward and finally received the final documentation of their dedication and high standards when it comes to quality management. This confirms a solid fundament for our continued work with regulatory processes, says CEO Joacim Holter at Lifecare.

- Safety, compliance and top-class quality are our unwavering guidelines in our market for medical devices. One thing is that there are demands from the authorities, but ISO certification also means something for the professional integrity of the employees, but also for the credibility of the company, says Senior QMS Manager Barbora Tencer.

According to the International Organization for Standardization (ISO) regulatory requirements are increasingly stringent throughout every step of a product's life cycle, including service and delivery. Increasingly, organizations in the industry are expected to demonstrate their quality management processes and ensure best practice in everything they do. This internationally agreed standard sets out the requirements for a quality management system specific to the medical devices industry.

In November CEO Joacim Holter commented on the successful audit. - It is vital for the integrity of the production of Sencell Continuous Glucose Monitor, and later commercialization of the product, that our Quality Management System are certified. We depend on the trust from the market and patient groups, that our processes meet international quality standards. It is therefore very motivating to successfully complete the ISO 13485 audit in accordance with the planned and

communicated timeline. This is solid confirmation that Lifecare's operations are compliant with the standards necessary to develop and produce medical devices. Lifecare will continue to improve our standards and quality systems to ensure regulatory compliance in our upcoming operations.

About us

Lifecare AS is a clinical stage medical sensor company developing technology for sensing and monitoring of various body analytes. Lifecare's main focus is to bring the next generation of Continuous Glucose Monitoring ("CGM") systems to market. Lifecare enables osmotic pressure as sensing principle, combined with the ability to manipulate Nano-granular Tunnelling Resistive sensors ("NTR") on the sensor body for read-out of pressure variations. Lifecare's sensor technology is referred to as "Sencell" and is suitable for identifying and monitoring the occurrence of a wide range of analytes and molecules in the human body.

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