PRESS RELEASE
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LIFE: SUCCESSFUL ISO 13485 AUDIT

Bergen, Norway, November 20th, 2023: 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 been successfully audited as part of the upcoming ISO 13485 certification.

Reference is made to Lifecare's list of trigger events, as presented at the semi-annual report of August 20th, 2023, and later investor communication. The launch of an automated production line at Lifecare Laboratory by end of Q2 2024 is set as a major milestone, and on this basis the company aim to launch the first product in the veterinary market mid 2024.

Last week, the ISO 13495 audit was conducted, and finalized, at Lifecare Laboratory. The purpose of the audit was to review Lifecare's Quality Management System in context of ISO 13485. The audit was concluded without any major findings, and consequently Lifecare Laboratory will be recommended for ISO 13485 certification.

Lifecare expect the ISO 13485 certificate will be issued early in 2024. This progress is in accordance with the current list of communicated trigger events. - Passing this milestone is a very important achievement for Lifecare, The Lifecare QMS-team in Bergen and Mainz has worked dedicatedly and systematically towards this goal and has proven their high standards, dedication and progress when it comes to quality management. This is confirming a solid fundament for our continued work on regulatory processes, says CEO Joacim Holter at Lifecare.

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. - Safety and quality are non-negotiable in the medical devices industry, that's why we decided to certify for the ISO 13485, 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 xpected 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.

Lifecare Laboratory was ISO 9001 certified in April 2023. To be also be compliant with ISO 13485 is an important step on the route towards Lifecare's ultimate goal; product CE mark necessary to enter the market with a medical device for humans.

- 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 Lifecares 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, says CEO Joacim Holter.

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.

Contacts

For further information, please contact:

Joacim Holter, CEO, Lifecare AS, **joacim.holter@lifecare.no**, +47 40 05 90 40

Asle Wingsternes, Head of Communications & Public Affairs, **asle.wingsternes@lifecare.no**, +47 41 61 42 52

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