PRESS RELEASE
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LIFECARE ADVANCES CE MARK PREPARATION FOR ITS GROUNDBREAKING MEDICAL DEVICE

Bergen, Norway, 13 August 2025 – Lifecare ASA (LIFE), a MedTech company developing next-generation Continuous Glucose Monitoring (CGM) technology for diabetes management, is pleased to announce that formal preparations towards CE marking of its CGM as a fully regulated medical device have been underway for the past six weeks.

Lifecare has started the formal preparations to document regulatory compliance and achieve CE mark for its CGM system as a fully regulated medical device, according to our communicated plan, by end of 2026. This phase encompasses the full CGM system - sensor, implant, reader, manufacturing processes, and comprehensive ISO 13485-compliant documentation, the international recognised quality standard for medical devices - firmly placing Lifecare on the regulatory pathway to market readiness.

“Initiating the full CE preparation phase – with substantial progress already achieved - is both a technical milestone and an important public statement of where we stand,” says Joacim Holter, CEO of Lifecare ASA. “It demonstrates our readiness to deliver a regulated medical device to market and our ability to build on the strong foundation already established through CE compliance work on the electronics of our proven implant.”

Lifecare has previously announced important compliance achievements for the electronics within our CGM system, with final CE compliance for the electronic components expected by end of Q3 2025. This advancement is a partial step towards full regulatory compliance for Lifecares CGM as a medical device.

Initiating CE mark preparations require more than having a working device – it demands proof that every device manufactured will meet the same rigorous standards of safety, performance and quality. This process is comparable to creating an end-to-end instruction manual and safety log for the entire lifecycle of the product – covering every design decision, supplier, material, and manufacturing step – and ensuring each one can be repeated exactly, without compromise. This proof comes from a formalised Quality Management System, supported by an extensive framework of interlinked, traceable and auditable documents, including detailed design records, risk analyses, supplier quality agreements, manufacturing instructions, inspection reports, and test protocols.

Such documentation is the foundation for regulatory approval, ensuring consistent, reproductible and safe manufacturing for human use. We are continuing our strong cooperation with TTP as a highly valued development partner, ensuring that we meet all the stringent regulatory standards required to deliver a device ready for market introduction.

As Lifecare advances through this complex and highly structured regulatory process, each completed step further solidifies our position as a company on the verge of market introduction – not only showcasing our technical capability but also sending a clear signal to stakeholders, partners, and the market that Lifecare is ready to deliver.

About us

Lifecare ASA is a medical sensor company developing technology for sensing and monitoring of various body analytes. Lifecare's focus is to bring the next generation of Continuous Glucose Monitoring ("**CGM**") systems to market. Lifecare enables osmotic pressure as sensing principle. Lifecare's sensor technology is suitable for identifying and monitoring the occurrence of a wide range of analytes and molecules in the human body and in pets.

Contacts

For further information, please contact:

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

Renete Kaarvik, CFO, renete.kaarvik@lifecare.no, +47 94 83 82 42