PRESS RELEASE
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LIFECARE SUBMITS UPDATED DOCUMENTATION TO NOMA: REGULATORY REVIEW RESUMES IN FIRST-IN-HUMAN STUDY APPLICATION

Bergen, Norway 5 February 2026 - Lifecare ASA (LIFE), a MedTech company developing next-generation Continuous Glucose Monitoring (CGM) technology for diabetes management, announces that it has submitted updated documentation to the Norwegian Medical Products Agency (NoMA) in connection with the Company's application to initiate its first-in-human clinical study.

The updated submission addresses the procedural and technical clarification points raised by NoMA in its preliminary assessment communicated on 11 December 2025. These clarifications relate to standard documentation expectations for first-in-human investigations of implantable medical devices under Regulation (EU) 2017/745 (MDR).

As previously communicated, NoMA's preliminary assessment did not raise any concerns regarding the scientific rationale, intended use, or overall risk-benefit profile of the planned study. The requested clarifications covered, among other things, documentation related to biocompatibility, sterilization processes, manufacturing controls, and the presentation of existing preclinical data, in line with applicable MDR guidance and standards.

Lifecare has prepared the updated documentation in accordance with NoMA guidance, relevant MDCG documents, and applicable ISO standards, and confirms that the response was submitted on 4 February 2026.

Following submission of the updated documentation, the regulatory review process resumes. As previously stated by NoMA, the agency has 26 review days remaining to complete its assessment and issue a decision, in accordance with standard regulatory procedures. Should NoMA request additional clarifications, the review timeline may be paused in line with normal regulatory practice.

Outlook

Based on current communication with NoMA and the remaining review timeline, Lifecare continues to expect a final regulatory decision within Q1 2026.

The application concerns a pilot first-in-human study designed to evaluate the accuracy and clinical performance of Lifecare's proprietary CGM system. The study is planned to be conducted at the University of Bergen, under the supervision of Professor Simon Dankel as Principal Investigator.

The first-in-human study represents an important step in Lifecare’s clinical and regulatory roadmap and will generate data supporting the Company’s planned pivotal CE-marking study.

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 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.

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