



## ProstaLund has submitted an application for CE marking of its new treatment platform

ProstaLund announces today that the company has submitted the technical documentation for its new platform to its notified body, TÜV SÜD. This is the final phase in the CE marking process of ProstaLund's new treatment platform CoreTherm® Eagle.

A notified body is an independent third party appointed by a competent authority to verify that the product is safe from a clinical, safety and user perspective. The CE mark verifies a company's clinical claims that a product meets the essential requirements of the Medical Devices Regulations (MDR), and it is a legal requirement for a product to be sold on the market within the EU. TÜV's evaluation is expected by the company to be completed during the first quarter of 2023. After obtaining the CE mark, the product will be available for sale in Europe.

CoreTherm® Eagle is an updated and modernized platform for performing ProstaLund's treatment of benign prostatic enlargement, CoreTherm® Concept. CoreTherm® Eagle combines the proven and well-documented technology from previous CoreTherm® platforms with a newly developed, simplified, and modern user interface and software updates in order to provide improved method support for treating physicians and increased safety for treated patients.

“The development work of CoreTherm® Eagle began long before I arrived at ProstaLund and after a re-start in the spring of 2020, it feels incredibly nice that we have now reached this milestone. This is a very important piece of the puzzle to be able to take CoreTherm® towards a wider use and we will now have full focus on planning and preparing for the launch of CoreTherm® Eagle.” comments CEO Johan Wennerholm

**For further information, please contact:**

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## About ProstaLund

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ProstaLund AB is a Swedish medical technology company and a leading developer and manufacturer of innovative urological devices and treatments. The company's lead product, CoreTherm, is a patented Thermotherapy treatment method for Benign Prostatic Hyperplasia (BPH) which can be tailored to suit the needs of each individual patient. CoreTherm is used today in hospitals and clinics in Sweden and worldwide. ProstaLund is listed on the Nasdaq First North Growth Market.

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## Attachments

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