



ProstaLund hosted unannounced audit by TÜV SÜD

ProstaLund has successfully hosted an unannounced audit by TÜV SÜD.

As per Medical Device Regulation (EU-MDR 2017/745), notified bodies are obliged to perform unannounced audits in the premises of manufacturers, its critical subcontractors or its crucial suppliers. TÜV SÜD therefore audited ProstaLund's contract manufacturer one day, and ProstaLund a half-day this week. The scope of the audit was the new platform CoreTherm™ Eagle. The audits yielded positive results with only one minor nonconformity.

The audits primarily checked the extent of conformity of ProstaLund's documentation for the new platform CoreTherm™ Eagle towards EU MDR 2017/745 and the Quality Management System standard ISO 13485:2016.

In addition to the unannounced audit, ProstaLund hosted a combined surveillance audit of EU MDR 2017/745 & MDD 93/42/EEC, and recertification audit of ISO 13485 in February. Even this audit of TÜV SÜD was successful and resulted in only one minor nonconformity. The scope of the audit was the complete Quality Management System and product portfolio of ProstaLund.

Based on comparative annual data from 2023, the number of audit findings has steadily decreased, indicating sustained quality of systems made even better through improvements implemented.

"I'm very pleased with the results and the continuous improvements being made by the team. ProstaLund stands strong and continues to prepare for the launch of CoreTherm™ Eagle" says Anders Kristensson, CEO of ProstaLund.

For further information, please contact:

Anders Kristensson, CEO
Tel. +46 (0) 769 42 12 16
Email: anders.kristensson@prostalund.com



PRESS RELEASE
12 April 2024 14:45:00 CEST

About ProstaLund

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.

Certified Adviser:

Västra Hamnen Corporate Finance AB

Phone: +46 40 200 250

E-mail: ca@vhcorp.se

Attachments

ProstaLund hosted unannounced audit by TÜV SÜD