

PolarCool Makes Key Regulatory Progress and Nears Launch in Canada

Med-tech company PolarCool AB (publ.) has completed its Stage 1 audit within the MDSAP (Medical Device Single Audit Program) and is now recommended for Stage 2 – the final step toward certification that will enable the launch of PolarCap® in several new international markets outside of Europe – particularly the Canadian market, of which the company targets with great importance.

PolarCool AB has successfully completed the Stage 1 audit within the MDSAP (Medical Device Single Audit Program) and is now recommended by Intertek Notified Body to proceed to Stage 2, the final step to obtaining the MDSAP certificate. This would allow PolarCap® to be launched in several new markets outside Europe, including Canada.

At the same time, PolarCool have had a positive discussion with Health Canada regarding the classification of PolarCap®. The outcome is that the product most likely will be a Class 2 product, which means a lower entry barrier for approval. This means that the company is now preparing for a launch in the Canadian market during the first quarter of 2026.

Canada represents a highly attractive and strategic market, particularly given the nation's passion for ice hockey. In the 2024/25 season, over 600,000 registered players participated in the sport, highlighting substantial potential for PolarCap® adoption across both professional and amateur clubs. Rugby also holds a strong presence in Canada, with more than 100,000 registered players nationwide.

The final step in the MDSAP process is the Stage 2 audit, scheduled for early November. Once completed, only product approvals for each target market will remain, with PolarCool anticipating Health Canada's approval in Q1 2026.

PolarCool CEO Erik Andersson comments:

- *We are very pleased and proud of the outcome of the Stage 1 audit, it's great to be moving forward in the certification process. Combined with the positive discussions with Health Canada, this gives us a clear path forward to launch PolarCap® in Canada. It's a major step toward our goal of establishing the product in the highly attractive North American markets.*

An MDSAP certificate for a company's quality management system (QMS) is a requirement for market approval in Canada. The certificate can also be used to apply for market approval in Australia, Brazil, Japan and the USA, although these countries also have their own separate approval processes, possible without an MDSAP certificate. In the USA, the plan remains unchanged – PolarCool aims to begin launching PolarCap® in Q4 2025, subject to market approval from the FDA.

For more information

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About PolarCool AB (publ.)

*PolarCool AB (publ.) is a Swedish medical technology company focused on developing and marketing products in the sports medicine field. Its primary product, **PolarCap®**, is designed to reduce the impact of concussion through targeted brain cooling. PolarCool works with professional teams across Europe in rugby, football, and ice hockey and its shares are listed on Spotlight Stock Market.*