

PolarCool receives MDR 2017/745 approval for the PolarCap® System

The medical technology company PolarCool (publ.) has received the MDR 2017/745 approval for the company's product PolarCap® issued by Intertek Medical. The approval enables PolarCool to be the legal manufacturer for the product.

PolarCool develops the product PolarCap®, which alleviates the effects of concussions. The primary customers are sports clubs and facilities in ice hockey, rugby, football, and handball, but also other sports with an increased risk of concussion.

In the ongoing MDR process with Intertek Medical, a Notified Body (NB), the company has obtained a certificate for the SmallCool unit, which is the portable cooling unit part of the PolarCap® System. The SmallCool unit is classified as a Medical Device IIa, and thus needs to be certified by a Notified Body for market approval. Together with the PolarCap HeadCap and the neoprene cover they make up the PolarCap® System.

With PolarCool now having both an ISO 13485:2016 certificate for its Quality Management System (QMS) and an MDR 2017/745 certificate for the PolarCap® System, the company can now itself be the legal manufacturer of the product. Currently, the PolarCap® System is certified through a co-operation agreement with BrainCool AB (publ.), which means that the product is manufactured and sold under BrainCool's QMS.

PolarCool CEO Erik Andersson comments:

- The fact that we have now received the two certificates, both for the QMS and for the product, required for PolarCool to be a legal manufacturer for the PolarCap® System is very positive news. Handling this process in-house, under our own banner, not only promises substantial cost savings for the company but also empowers us to independently approve new products in the future.

This information is information that PolarCool (publ.) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out herein, on October 25th, 2023.

For more information

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About PolarCool AB (publ.)

PolarCool AB (publ.) is a medical device company that develops, markets, and sells products for sports medicine. The company focuses on treatment of concussive and sub-concussive brain injury with the portable cooling device PolarCap® System. PolarCool AB (publ.) is based in Lund, Sweden, and its shares are listed on Spotlight Stock Market.