Press Release
26 January 2023 08:15:00 CET

Perimed today announces that the company's products, quality system and manufacturing facility has been certified in accordance with the new European Medical Device Regulation (MDR)

Safety and effectiveness are focus areas for us as a medical device company. By continuously adapting to meet the Quality and Regulatory requirements during the product life cycle through an effective and practical Quality Management System and procedures, we maintain our competitive edge.

"*Our vision is to save limbs, lives and reduce human suffering and one of our value statements is to have Compliance in everything we do. I am so proud to have our team deliver on this important milestone without receiving any non-conformances.*", says Lena Åredal, CEO at Perimed.

The European Medical Devices Regulation 2017/745 (MDR) is applicable in Europe, replacing the Medical Devices Directive (93/42/EEC) and introducing major changes to how medical device manufacturers obtain European market access. This transition involves an increased work effort compared to the previous regulation, since the MDR introduces a life-cycle approach for the CE Marking Compliance and introduces several new requirements.

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About Us
Perimed is a private Swedish company active on the global market, with seven subsidiaries and more than twenty distributors around the world. We have more than 40 years of experience and unique competence in laser-based blood perfusion measurements, making Perimed a leader in peripheral vascular diagnosis. Our equipment is typically used in Wound Care Departments, Diabetic Foot Clinics, Vascular Surgery/Labs and Radiology. We have over 4000 installed instruments worldwide.

Attachments
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