

Vigmed granted Quality System Certification

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Vigmed, having completed the establishment of a Quality Management System, and has now been granted Quality System Certificate for both EN ISO 13485:2012 and EN ISO 9001:2008 (issued by Presafe A/S). The scope of the Certification includes development & manufacturing of solutions to prevent needle stick injuries.

The 13485:2012 standard includes Quality Management System requirements for medical devices specifically for regulatory purposes. It is based on the ISO9001 standard and is also harmonized with FDA regulations. It provides a framework for a manufacturer to meet the Quality System Requirements for the registration of medical devices.

“The certification for the 13485 and 9001 standards supports Vigmed’s ambitions to launch a new product every year, and will provide further assurance that Vigmed management processes will constantly evolve and improve in regards to both effectiveness and efficiency”, says CEO Finn Ketler.

Vigmed is a Swedish medical technology company whose mission is to eliminate needlestick injuries by offering the market unique needle-protected products. Vigmed is headquartered in Helsingborg, Sweden, and has approximately 15 employees. Vigmed's share is traded on NASDAQ OMX First North in Stockholm (ticker VIG) and has approximately 5 400 shareholders. Remium Nordic AB is the Company's Certified Advisor. Additional information such as company description, a video presentation and risk factors can be found on Vigmed's home page: www.vigmed.com/investor