Ortivus receives MDR certificate

We are very proud to announce that Ortivus has been certified under the Medical Device Regulation (MDR) and that MobiMed continues to be a CE marked medical device. The certification means that our medical technology solutions are now compliant with the new European legislation for medical technology products, that was installed to guarantee patient safety.

Ortivus has worked actively with the certification process for the past two years and on November 28, 2023 the company received its EC certificate with Ortivus MobiMed AB as the legal manufacturer. MobiMed has been CE marked under MDD for a long time.

"We are very happy to have received the certificate as many companies/products are still waiting to become certified. We are extra proud to be one of the first Swedish manufacturers of mobile patient monitoring systems to be certified and that we can continue to compete internationally." - says Magnus Mårtensson, Chief Product Officer and Deputy CEO.

The certification of Ortivus and the CE marking of MobiMed under the MDR has been made possible thanks to Ortivus' competent employees. We have also benefited greatly from the fact that all functions, from development, quality and production to marketing, sales, and service, are under the same roof at our headquarters in Danderyd, Sweden.

About the Medical Device Regulation (MDR)
The European medical technology industry has since 26 May 2021 been regulated by the Medical Device Regulation (MDR). The MDR aims both to achieve high safety and quality in medical devices that are manufactured, imported into, or sold within the EU. All products need CE marks under the MDR certificate to be marketed and sold within the EU.

The MDR creates a robust, transparent, sustainable, and internationally recognised framework that focuses on improved clinical safety. The MDR is thus a regulatory framework and replaces the former Medical Device Directive (MDD), which is a directive with fewer requirements, that does not have to be incorporated into national legislation.

Ortivus is today certified according to ISO 13485, ISO 27001 and ISO 20000-1. The certified management systems together with the EC certificate of the MDR enable us to CE mark our medical technology solutions under the MDR.

Contacts

For further information, please contact

Reidar Gårdebäck, CEO

Telefon +46 8 446 45 00

About Ortivus

Ortivus develops and commercialises MobiMed, e-health and medical technology solutions for a safer and more efficient healthcare. The company was founded in 1985 and is today a leading provider of mobile digital solutions for prehospital care, worldwide. Ortivus' innovations are based on in-depth expertise in cardiology as well as decades of development together with users and customers. The company's headquarters are located in Danderyd, Stockholm. The company has, since 1998, a wholly owned subsidiary based in the United Kingdom and since 2022, a wholly owned subsidiary based in Denmark.

MobiMed is a modular platform that connects and enable real-time information sharing throughout the prehospital care chain. It is currently used by over 12,000 paramedics in over 2,700 emergency vehicles. The platform, MobiMed, consists of several product modules that are completely integrated but can also be used stand-alone. MobiMed comprises four main solutions: MobiMed Monitor, that measures, monitors and shares patients' vital parameters and ECG in real-time, MobiMed ePR, - an electronic patient record for decision support, collection of patient data and clinical documentation, MobiMed enRoute, - a tool for navigation and case management, and MobiMed Life - a range of stand-alone defibrillators.

MobiMed saves vital seconds and enable healthcare professionals make the right decisions in critical situations. MobiMed also contributes to improved quality of care and saved resources.

Ortivus Class A and Class B shares are listed on the NASDAQ Stockholm Small Cap list.

Read more about Ortivus at www.ortivus.com

This information is information that Ortivus is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-11-29 08:30 CET.

Attachments

Ortivus receives MDR certificate