Pressrelease

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Raytelligence receives MDR labeling from the Medical Products Agency

EaZense has been registered with the Medical Products Agency and certified under MDR. This means that the product is approved in accordance with the EU regulation on medical devices that ensures the safety and performance of medical devices.

EaZense has been CE marked according to previously applicable directives for medical devices, MDD. The EU's new Medical Devices Regulation (MDR) replaced the MDD in May 2021.
Like all medical technology companies with products on the European market, Raytelligence has had to adapt its operations to meet the new requirements for CE marking of the products.

"*Our sensorsystem EaZense has been registered with the Medical Products Agency and certified under MDR. The MDR certification is important because it certifies that the product continues to meet the EU's essential health, safety and environmental requirements. The application was submitted on 26 May"* says Klas Arvidson, CEO Raytelligence

About the EU regulation
The regulation updates the rules on which medical devices may be on the market, and how products are provided and used. The regulation improves patient safety by introducing stricter methods for assessment and monitoring in the market. It also contains rules for how medical technology companies conduct product evaluations within the EU. This ensures that unsafe and incompatible products and equipment do not end up on the market.

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RAYTELLIGENCE

About Raytelligence AB (publ)

Raytelligence is a Swedish innovation company, based in Halmstad that offers products for monitoring vital parameters, ie breathing, heart rate and movement patterns, based on the company's own 60 GHz radar technology.