

MyOr Receives Industry-First EU-MDR Certification for MyorCare® AI Platform

MyOr's flagship food allergy prediction platform becomes the first-and-only AI food allergy educational platform certified as a medical device under EU-MDR

TEL AVIV, ISRAEL, June 18, 2024 /EINPresswire.com/ -- [MyOr](#), a global leader in pediatric AI



This is a major regulatory milestone for MyOr on the international stage."

Dr. Ariel Katz, CEO

solutions, today announced that its MyorCare® risk assessment and educational platform has been registered as a Class I medical device under the European Union Medical Device Regulation (Regulation (EU) 2017/745) (EU-MDR). The certification positions MyOr as the first company worldwide in the AI-driven food allergy education industry to obtain the new European Medical Device

Regulation (MDR) Certification recommendation.

The EU-MDR is one of the world's most stringent health tech regulations, playing a crucial role in ensuring medical devices meet the highest standards of safety and efficacy. This certification supersedes any previous EU Medical Devices Directive (MDD) certification that previous versions of MyorCare® received.

"The EU-MDR is among the world's most robust health tech regulations, and it plays a vital role in ensuring medical devices meet the highest standards" said Dr. Ariel Katz, CEO and co-founder of MyOr. "Our certification demonstrates the quality and care we apply in the development and maintenance of our AI systems and products, and is testament to our team's dedication to delivering health AI that meets and exceeds the most stringent standards and best practices in healthcare technologies."

MyorCare® uses advanced algorithms and machine learning to assess and predict health risks such as food allergies and atopic dermatitis from infancy. To secure Class I classification, MyOr had to consistently demonstrate that its MyorCare® solution and quality management system met the EU-MDR's rigorous standards for safety and effectiveness. This involved undergoing external audits, submitting comprehensive technical documentation, and providing evidence of clinical benefits and studies for review.

"As we continue to lead the industry forward with tailored educational solutions for the global health market, MyorCare®'s EU-MDR certificate will reinforce the confidence of parents across

Europe that we are delivering the highest standard of care for their children's health, safety and wellbeing ," said Dr. Michael Brandwein, CTO and co-founder of MyOr.

Although the EU-MDR certification is only applicable within Europe, Myor's quality management system, as certified by the Israel Standards Institute, is also compliant with several global standards to ensure the medical software quality and safety.

Parents can begin using MyOr's MyorCare® today by visiting www.myorcare.com/survey.

About MyOr: MyOr is a pioneering infant and maternal health through MyorCare® - an innovative, evidence-based educational tool specifically designed to help parents understand and manage their child's health from the earliest stages of life. MyorCare® utilizes advanced algorithms and machine learning to assess and predict health risks such as food allergies and atopic dermatitis from infancy. This cutting-edge technology allows parents to take proactive steps in safeguarding their children's health, providing tailored educational resources that emphasize the importance of early interventions. MyOr is dedicated to empowering parents with the knowledge and tools they need to achieve optimal health and well-being for their children. We are committed to leading the industry forward by providing high-quality, accessible, and practical educational tools that meet the needs of families across Europe.

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