

## Press release

### **PGXperts receives certification of its quality management system according to EN ISO 13485:2016**

**Fürth, September 13, 2024 - PGXperts has successfully received certification of its quality management system according to EN ISO 13485:2016 as software manufacturer of medical devices for the provision of information for the verification of pharmacogenetic and pharmacological interactions.**

PGXperts GmbH has successfully certified its quality management system by TÜV Rheinland according to EN ISO 13485:2016. The MedTech company thus meets the highest regulatory requirements for a quality management system for the production of software as a medical device. The scope of the certification includes the design and development, manufacture, installation and distribution of the PGXperts System.

*"Quality and safety are the foundation of our daily work. We are very proud to have achieved this special milestone of ISO certification just eight months after our spin-off. This underscores our commitment to the highest standards to increase patient safety and enable personalized medicine."*

*- Herna Muñoz-Galeano, Founder and Managing Director of PGXperts GmbH*

### **PGXperts - Personalized Medication using Pharmacogenetics**

PGXperts enables personalization of current and future medication with the aim of increasing drug therapy safety. The PGXperts system provides physicians with evidence-based applicable knowledge about the interaction between drugs and a patient's genetically determined metabolic characteristics. With information on specific interaction risks (drug-genes, drug-drug, drug-food) the medication can be checked individually for a patient. PGXperts interprets genetic characteristics and provides the results to the treating physician in the form of clinical consequences and concrete measures.

### **Quality management system according to EN ISO 13485:2016**

The EN ISO 13485:2016 standard specifies the regulatory requirements for a quality management system for manufacturers and suppliers of medical devices. The aim of the ISO standard is the manufacture of safe and reliable medical devices in the EU.

## About PGXperts GmbH

PGXperts GmbH was founded in 2024 as a spin-off of HMG Systems Engineering GmbH. PGXperts is a MedTech company based in Fürth, Germany, that specialises in using pharmacogenetics to enable personalized drug prescriptions for every patient, everywhere, at any time. 41 employees from 6 different countries work on the innovations, which have already won several awards: IHK-Gründerpreis Mittelfranken 2019 | TOP 100 most innovative companies among German SMEs 2016 | 2nd prize PerMediCon Award 2016.

For more information, please visit: [www.pgxperts.com](http://www.pgxperts.com)

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