Quibim scores CE mark and UKCA certification for QP-Prostate®

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- **Securing the CE mark as a class IIb device, sets Quibim as a leader in the market, making QP-Prostate® one of the first AI products approved by the new MDR regulation.**
- **QP-Prostate® is an innovative AI-based MRI solution, designed to increase diagnosis accuracy and early detection of prostate cancer.**
- **This milestone builds on top of existing Quibim achievements in life sciences, linking real world evidence research to the creation of best-in-class medical devices for providers.**

Valencia, Spain, October 27th, 2022. Quibim, a company designing pioneering AI tools to unlock imaging data to improve patient outcomes, has reached a key milestone by obtaining MDR (class IIb) and UKCA certifications. This allows the company to commercialize QP-Prostate® in the European and British markets after launching the solution in the US, with FDA 510k clearance in 2021. The new regulatory stamps make QP-Prostate® one of the first AI products cleared under this new and demanding regulation.

"This is a big step for Quibim as it makes QP-Prostate® available to radiologists, hospitals and pharmaceutical companies in Europe and the UK. It also highlights our commitment to quality and regulatory processes, following the highest standards given by higher risk classifications as the class IIb. In fact, we also received ISO27001 certification for information security last month, meaning that we have implemented a safe and effective imaging data management strategy, working with the biggest imaging biobanks in Europe, combined with best and safe medical devices." explains Angel Alberich Bayarri, CEO of Quibim. From this perspective, obtaining these certifications is not only a big achievement for the company but also for the AI sector, as the number of CE-marked AI-based radiological software solutions listed in "AI for Radiology" is currently 202, of which only 18% are MDR certified.

Prostate cancer affects around 1.4 million patients worldwide, making it the second most common type of cancer in men. With almost 1 in 8 men diagnosed with this disease in their lifetimes, early detection is critical, although it represents a challenge for urologists since prostate cancer is asymptomatic in its initial phase. Current diagnostic tools, such as blood tests for prostate-specific antigen (PSA) levels, have well-known limitations and can lead to unnecessary biopsies in patients or biopsies without accurate target.

To improve diagnostic accuracy, Quibim created QP-Prostate®, an innovative software that uses AI to streamline prostate MRI interpretation and pre-populate radiology reports, with the aim of increasing early detection of cancer and increasing life expectancy of patients. This software won the EuroMinnies Award as Best New Radiology Software of 2022 as the only tool that performs automated regional segmentation of the gland and seminal vesicles based on convolutional neural networks (an artificial intelligence technology applied directly to images). QP-Prostate® can reduce interpretation time and help define regional diagnosis faster. "In addition to analyzing the prostate as a whole, this tool detects the different regions of the prostate and surrounding structures, including advanced functionality to segment anatomical zones defined in the PI-RADS 2.1 (Prostate Imaging Reporting and Data System) guidelines," points out Josep Hortigüela Zamora, Director of the Quality Department.

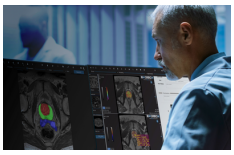
Quibim is at the forefront of medical imaging research and envisions non-invasive prostate MRI becoming a routine screening test for cancer detection. “At Quibim we work to transform images into actionable predictions that improve the quality of life of patients. With QP-Prostate®, we want to standardize prostate MRI exams for men similar to what exists with mammograms with women. This in turn, reduces the workload of radiologists, increasing the knowledge that can be extracted from the MRI images and improving detection and diagnosis,” concludes the company’s CEO.

Quibim’s prostate cancer pipeline

Quibim works in partnership with the top pharmaceutical companies contributing to their case studies by using advance knowledge and creating new imaging biomarker panels as predictors of clinical outcomes in prostate cancer and other solid tumor diseases. The company has an established relationship with Janssen for example, predicting outcomes in advanced stage prostate cancer patients, to identify patients at risk early and treat them accordingly.

Regarding data access, the company is a key partner in the Chaimeleon and the ProCancer-I European

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consortiums, which are aggregating the imaging studies and multi-omics data of 20.000+ prostate cancer patients. In the long term, the company has initiated projects to build a digital twin of the prostate gland through the ProCanAid project.

About Quibim

Quibim was born from the ambition of transforming imaging into a catalyst for precision health, designing pioneering tools that unlock imaging data to improve patient outcomes. The brand is linked to company values, based on a deep foundation in science and expertise in transforming imaging data into actionable predictions. Quibim partners with top-tier biopharma companies to detect pathologies early and predict outcomes in oncology/immunotherapy, rheumatology and neurology using imaging multi-modalities such as MRI, CT and PET. The company is specialized in large networks to advance the development of AI models and help real-world evidence (RWE) projects and biopharma partners extract new insights from images; developing novel quantitative imaging biomarkers to deeply analyze disease mechanisms, advance drug discovery and monitor treatment progress using a whole-body approach.

Quibim leads RWE studies with 10M+ de-identified research imaging registries from 50.000+ oncology patients.

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