Proposal for assessment of new health technologies

Important information – read this first!

- Submitted proposals for national health technologies (HTAs) will be published in full. If the proposer thinks there is information necessary for filling out the form, that should not be made public, please contact the secretariat (Nye Metoder) before submission.

  The proposer is aware that the form will be published in its entirety (tick): ☒

- Proposer has filled out point 19 below «Interests and, if any, conflicts of interest» (tick): ☒
- This form serves the purpose to submit proposals for health technology assessment (HTA) at the national level in Nye Metoder - the national system for managed introduction of new health technologies within the specialist health service in Norway. The form does not apply to proposals for research projects. A health technology assessment is a type of evidence review, and for this to be possible, documentation is required, e.g. from completed clinical trials. Lack of documentation may be one of the reasons why the Commissioning Forum (Bestillerforum RHF) does not assign a health technology assessment.
- If the proposal concerns a medical device, the proposer is familiar with the document «Guidance criteria for management of medical devices in the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway» (link) (tick): ☐

Contact information:

Name of the proposer (organization / institution / company / manufacturer)**:**

Quibim, S.L.

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Date and locality:

23rd May, 2025. Valencia, SPAIN

1. Proposer's title on the proposal: *
   *This may be changed during the course of the process"

QP-Prostate®, AI-based Medical Device for detecting clinically significant prostate cancer.

2. Brief description of the health technology proposed to be considered:

Prostate cancer is the second most common cancer in men, representing a significant public health concern. While MRI scans are essential for early detection, the growing demand has surpassed the availability of radiology experts, with diagnostic delays and inconsistencies in interpretation as direct consequences. Only a minority of the medical community consistently follows PI-RADS v2.1 guidelines.

QP-Prostate® introduces enhanced diagnostic capabilities by automatically analysing multiparametric or bi-parametric prostate MRI:

- Ensuring compliance with PI-RADS v2.1 guidelines to verify MRI acquisition protocol

- **Accurately segmenting the prostate gland** and calculating the total volume to **assist in PSA density calculations** [2]

- Performing **diffusion analysis** to extract clinically meaningful information that allows the detection of suspicious findings.

- **Efficiently identifying** suspicious lesions, highlighting regions of the prostate suspicious for **clinically significant prostate cancer** (csPCa), including a risk level classification: high or moderate, with a maximum of 4 potentially suspicious lesions. As this algorithm has been trained using biopsy outcomes as its ground truth, it provides clinically relevant insights beyond the limits of human visual interpretation. The prediction is an indication of the probability the lesion will be diagnosed as csPCa through a biopsy and not based on the radiological interpretation of the physician.

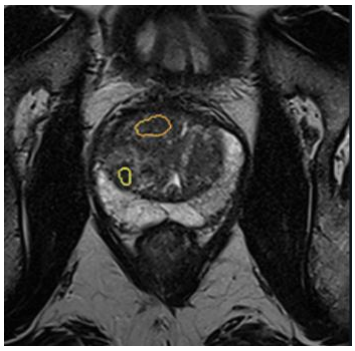

Figure. QP-Prostate csPCa outputs: bounding box in yellow (Moderate) and red (High), overlaid over the T2w sequence.

These features allow QP-Prostate to **enhance the radiologists' diagnostic performance**, with an **increase in sensitivity** by 4.8% **and specificity** by 2.4%, **catching missed cancers while maintaining a high negative predictive value (above 98%)**, thus enhancing clinical decision-making and supporting **more accurate diagnosis of prostate cancer**. The relevant clinical data is available in the FDA clearance documentation.

The results can be displayed in a variety of DICOM outputs and directly on hospital's Picture Archive and Communication Systems (PACS), ensuring seamless incorporation in the standardized clinical routine with no disruptions to radiologists' workflow.

QP-Prostate® is intended for image processing and analysis of prostate MRI. The application should be used by trained medical professionals, including but not limited to radiologists, urologists and oncologists. Additionally, the device is currently integrated as input in fusion biopsies, aiming to specifically streamline intraoperative workflows with urologist.

Also, Quibim is currently engaged in a multi-year collaboration with Johnson and Johnson to predict metastasis development, enabling the advancement of effective treatments. This new functionality will be integrated into QP-Prostate®.

3. Brief description of current standard of care (SOC) (Which health technology (ies) are currently used. What is the status of the technology (ies)? Whether it provides curative treatment, life extension, etc.)
Will the proposed technology replace or be a supplement to today's SOC?

In Norway, men with suspected (high PSA and/or suspicious clinical or digital rectal examination) or confirmed prostate cancer (PCa) are referred to the Prostate Cancer Package Course. They are evaluated, as part of the Standard of Care, using prostate multiparametric MRI (mpMR), which helps detect clinically significant disease and inform the decision to perform a biopsy. QP-Prostate® is designed to be used alongside the conventional Prostate Cancer clinical pathway to not only efficiently identify suspicious lesions, but also, to display all of its results in a variety of DICOM outputs and directly on hospital's Picture Archive and Communication Systems (PACS), by ensuring seamless integration into the standardized clinical workflows with no disruptions to radiologists' workflow. The technology **improves the radiologists' diagnostic performance**, enhancing clinical decision-making and supporting **more accurate diagnosis** of prostate cancer. The relevant clinical data is available in the FDA clearance documentation.

4.

This proposal concerns:	Yes	No
A brand new and innovative health technology	☒	☐
A new application, or a new indication for an established method	☐	☒
A comparison between several methods	☐	☒
A technology that is already in use	☐	☒
If yes – technology used in clinical practice	☐	☒
If yes – technology used in research/clinical trials	☐	☒
A re-evaluation of technology used in clinical practice	☐	☒
The technology is relevant for disinvestment	☐	☐

N/A

5. This health technology involves (Multiple ticks are possible)

Pharmaceutical	☐
Medical device/IVD medical device that is CE-marked*	☒

QP-Prostate® is a class IIb CE-marked device according to Regulation (EU) 2017/745, Annex IX Chapter I and III (Certificate No. MDR 752989 R000, first issued on 12th October 2022). QP-Prostate® is available in the EU market from 7th December 2022. QP-Prostate® has also received UKCA marking and FDA 510(k) clearance.

Medical device/IVD medical device that is not CE-marked	☐
Procedure	☐
Screening	☐
Highly specialized services / national offers	☐
Organization of the health services	☐
Other (describe)	☐

N/A

6. Application of the technology:

Prevention	☒
Assessment and diagnostics	☒
Treatment	☐
Rehabilitation	☐
Specialist health care	☐
Primary health care	☐

Prevention to help with National Screening Programs. Assessment and diagnostics to help with enhanced diagnostic capabilities by automatically analysing multiparametric or bi-parametric prostate MRI.

7. Responsibility for funding

	Yes	No
Is the specialized health service responsible for financing the technology today?	☐	☒
May the specialized health service become responsible for funding the health technology?	☒	☐

We understand that the funding source for the Software as AI-based Medical Device (SaMD) for Prostate Cancer has not yet been determined, and we believe that establishing this will be a crucial step in the future reimbursement process.

8. Is the technology mentioned in the national guidelines or action programs prepared by the Norwegian Directorate of Health?

Yes	No
☐	☒

We understand that the National Action Program, which includes guidelines for «Investigation, Screening for Prostate Cancer (Oslo 2016)», would be the relevant framework for the use of QP-Prostate®.

9. Does the technology involve the use of radiation (ionizing/ non- ionizing)?

Yes	No
☐	☒

N/A

10. Which discipline(s) does the health technology apply to, and which patients are affected? (Could the health technology also affect other groups (e.g. health personnel or relatives)?)

QP-Prostate® is a medical imaging processing application intended for image processing and analysis of prostate MRI. The application should be used by trained medical professionals, including but not limited to radiologists, urologists and oncologists. Patient management decisions should not be based solely on the results of QP-Prostate®. The software can be used in combination with a DICOM viewer and segmentation tool that allows for image visualization and user interaction.

QP-Prostate® analyses and quantifies medical images of:

-Patients with symptoms of prostate diseases for which T2 axial and DWI sequences that include the prostate region have been acquired

-Patients with suspicion of prostate cancer for which at least T2 axial and DWI sequences that include the prostate region have been acquired.

The intended patient population meets the following demographic characteristics: patients above 18 years with prostate MRI imaging; for the use of QP-Prostate®, image sequences that meet the minimum recommended image acquisition protocol must be available.

11. Which aspects are relevant to the assessment? (Multiple ticks are possible)

Clinical efficacy	☒
Safety/adverse effects	☐
Costs/resource use	☐
Cost-effectiveness	☒
Organizational consequences	☒
Ethical	☐
Legal	☐

12. Please suggest the main scope/objective for the health technology assessment, as well as secondary scopes/objectives (in compliance with question 10). For those familiar with “PICO” (Patient, Intervention, Comparator, Outcome) – please include tentative suggestions for PICO.

Patient:
Men above 18 years **with suspected** prostate cancer (i.e., elevated PSA and/or positive DRE findings and/or other symptoms) undergoing a prostate MRI exam as part of the Standard of Care, which enables the detection of clinically significant disease and inform the decision to perform a biopsy.

Intervention:
Use QP-Prostate® with the already obtained Prostate MRI and interpret its results adjunctively with other imaging and clinical information during radiological assessment to determine whether a biopsy is needed.

Comparator:
Current clinical practice. At the moment, the radiologist assessment without the support of QP-Prostate is used to inform biopsy recommendation.

Outcome:
Clinical effectiveness - clinical validity: the ability of QP-Prostate® to enhance diagnostic capabilities by automatically analyzing multiparametric or bi-parametric prostate MRI. This is made by accurately segmenting the prostate gland to assist in PSA density calculations; performing diffusion and perfusion analysis to extract clinically meaningful information that allows the detection of suspicious findings, and **efficiently identifying suspicious lesions**, highlighting regions of the prostate suspicious for clinically significant prostate cancer (csPCa), including a risk level classification.

Regarding diagnostic accuracy, a pivotal, randomized, retrospective, multi-reader, multi-case study conducted at Mass General Brigham Hospital demonstrated that the use of: QP-Prostate® significantly **improved radiologists' diagnostic performance**. The software led to an improvement in sensitivity by 4.8% (ranging from 2.1% to 7.5%) and specificity by 2.4% (ranging from -1.4% to 5.9%) at the lesion level, thus enhancing clinical decision-making and supporting more accurate diagnosis of prostate cancer. The relevant clinical data is available in the FDA clearance documentation.

Figure. Results of the impact of QP-Prostate on radiologist diagnostic accuracy.

Also, QP-Prostate® has demonstrated a significant impact on the efficiency of prostate MRI analysis. A pilot study conducted at the National Defence College in Japan showed that: **QP-Prostate® reduces prostate MRI reading times by 35.4%-58.8%**, a reduction that has the potential to increase radiologist productivity at a time when burnout is a growing concern across healthcare systems. This improvement in productivity could also translate into substantial cost savings for healthcare institutions, making QP-Prostate® a potentially *cost-effective* technology.

QP-Prostate **enables earlier intervention** and **potentially reduces healthcare costs per patient**, ultimately optimizing downstream costs and improving overall efficiency.

13. Please give a brief explanation of why it is important that the health technology assessment proposed should be conducted.

Prostate cancer is one of the most common types of cancer among men, with approximately 1 in 8 men being diagnosed during their lifetime. Early detection is crucial for successful treatment and improved survival rates.

Men with suspected prostate cancer (i.e., elevated PSA and/or positive DRE findings and/or other symptoms) are evaluated as part of the Standard of Care using prostate MRI, which helps detect clinically significant disease and inform the decision to perform a biopsy.

Despite advances in diagnostic tools like pre-biopsy MRI, the following challenges continue to complicate prostate cancer management, highlighting the need for more efficient and accurate solutions:

- Time-consuming data reading. Manual process of analyzing MRI is often slow and labor-intensive, which can delay diagnosis and treatment decisions. This is especially critical at a time when radiologists are experiencing considerable burnout due to the growing demands.
- Ensuring consistent image quality across different clinical settings and imaging equipment is challenging.
- Highly dependent on radiologists' expertise, leading to inconsistencies in interpretation. Different factors such as image quality, tumor visibility, and inter-observer variability can affect the results.

This often results in:

- **missed diagnoses**, around 16-30%.
- **or unnecessary biopsies**, which carry risk such as infection and trauma.

QP-Prostate® addresses these challenges by leveraging advanced AI algorithms to automatically segment the prostate and identify suspicious lesions, while also ensuring compliance with established guidelines. By automating the analysis of MRI data, QP-Prostate significantly reduces the time and effort required for diagnosis, ensures consistency in interpretation, reducing inter-observer variability and improving the overall accuracy of prostate cancer detection. This ultimately leads, as demonstrated by the previously mentioned study, to fewer missed diagnoses and unnecessary biopsies, improving patient outcomes and streamlining clinical workflows.

14. Please comment on the technology that is proposed to be assessed with regard to the following points:

The severity of the disease/condition the health technology targets

Prostate cancer is the most common form of cancer among men in Norway. About 5,000 people are diagnosed with this disease each year and 865 people died because of it in 2023.

QP-Prostate® is designed for investigating this severe illness; prostate cancer.
Whilst early stage prostate cancer is associated with a more favorable prognosis compared to other cancers the consequences of over and undertreatment with prostate biopsies are severe for patients.

Unnecessary biopsies may subject healthy patients to avoidable pain, discomfort, false-negative or false-positive results, bleeding, and even serious infections. Failing to identify patients who genuinely require a biopsy not only exposes those without clinical need to these risks, but also delays access to timely diagnosis and treatment for those who do need it—potentially leading to later-stage detection and reduced survival rates.

Expected effect

QP-Prostate® has a large potential benefit in Norway, but the following effects merit particular attention:

- QP-Prostate® improves clinical workflow through reduced reporting times and integration with fusion biopsy devices

QP-Prostate® delivers **market-leading prostate segmentation accuracy** (88%) [2], using deep learning to delineate the gland and its key subregions—Peripheral Zone (PZ), Central + Transitional Zones (CZ+TZ), and Seminal Vesicles (SV). It also identifies PI-RADS v2.1 regions and **calculates prostate volume, enabling PSA density computation and supporting fusion biopsy planning**.

Automating volume estimation **eliminates manual measurements** typically required from radiologists, streamlining PSA density reporting. A study that used a deep learning model to segment the prostate gland on T2-MRI, proved that in a 100-patient test set alone**, the model saved nearly 16 hours of segmentation time**, outperforming conventional models and trained radiology technicians [8].

- QP-Prostate® improves radiologists' diagnostic accuracy, increasing the number of detected PCa cases and avoiding unnecessary biopsies; and reduces the variability across radiologists

QP-Prostate® uses advanced deep learning to automatically detect clinically significant prostate cancer (csPCa) lesions with high accuracy and efficiency. Trained on biopsy-confirmed pathology data, the AI model analyzes biparametric MRI inputs (T2W and DWI) to **identify suspicious regions and classify them as Moderate or High risk**. The system combines unsupervised learning to detect and cluster potential lesions (excluding volumes <0.1 mL), followed by a supervised classifier trained using Gleason score ≥7 as ground truth.

While QP-Prostate® performs the same task as radiologists—identifying lesions suspicious for csPCa—it does so differently. Radiologists rely on the PIRADS 5-point scale based on lesion appearance across MRI sequences (T2W, DWI, and optionally DCE). In contrast, QP-Prostate® is **trained directly on biopsy-proven outcomes**, enabling it to **detect imaging patterns linked to csPCa that may not be visually apparent**.

Also, radiologists use QP-Prostate® alongside MRI studies to support the detection and localization of suspicious lesions requiring further diagnostic workup, such as biopsy. Clinical studies show that **radiologists assisted by QP-Prostate® achieve significantly higher diagnostic accuracy and sensitivity** (positive, statistically significant differences in AUC), **while also showing a trend toward reduced unnecessary biopsies** and **increased inter-reader variability** (both non-statistically significant).

To evaluate the standalone performance of the automatic lesion detection algorithm, Quibim conducted a retrospective study involving 228 cases as part of a multi-reader, multi-case study at Mass General Brigham Hospital. The detailed study design and case characteristics are presented below. QP-Prostate standalone performance is comparable to radiologists', with sensitivity and specificity in high-marker cases at 68.5% and 74.2%, respectively; and in moderate-marker cases at 79.5% and 59.2%. Given its intended use as a decision support tool, the objective is to improve radiologists' accuracy rather than serve as a direct replacement or comparison.

In summary, the result of using QP-Prostate® is the **improvement of decision-making processes to ensure best patient outcomes**, optimizing image interpretation workflow and streamlining diagnostic process.

Safety

Patient management decisions should not be based solely on the results of QP-Prostate®. The benefits of QP-Prostate® outweigh the identified risks. QP-Prostate® is considered safe when used as intended. QP-Prostate® has no known undesirable side-effects. The user is advised to carefully observe the residual risks communicated as limitations, contraindications, precautions and/ or warnings throughout the Instructions for Use

Total number of patients in Norway the health technology is applicable to

We should take into account that the intended use is for male patients patients above 18 years with prostate MRI imaging, and this usually happens after they turn 45, making this technology potentially applicable to more than 1,255,000 patients.

This number is obtained through the following calcutions: according to Statistics Norway, at the start of 2025, there were 2,492,360 people aged 45 and older in the country; and of this, 50,39% of them would be men, according to the World Bank.

This means that **QP-Prostate® could potentially improve the outcomes of the MRI results for almost 22% of the Norwegian population and improve prevention in all men above 18 years old**. Additionally, it will undoubtedly improve the lives of more than 5,000 men diagnosed with the disease each year.

It is also important to note that the population has been aging, with an increase in people aged 67-79 and over 80. This directly impacts the potential increase in diagnoses of prostate cancer, as it is more common for the prostate to develop lesions as men age. These lesions may be classified as clinically significant prostate cancer or not, but what is certain is that the number of MRI readings used to determine these lesions will increase, and QP-Prostate® would greatly help in the accuracy of those readings.

Consequences for resource use in the public health service

QP-Prostate® is not expected to have major budgetary implications for the specialist health service. Use of the tool is expected to be cost-saving or cost-effective. The main consequences of using QP-Prostate® would be:

-**Reduction of unnecessary biopsies**. Savings can be accrued via lower total costs for biopsies due to the overall reduction in the number of patients doing unnecessary ones. This includes costs for drug acquisition, administration, monitoring, supportive treatments, and management of related adverse events.

-**Earlier detection**. This can significantly reduce healthcare costs because, helping to identify the disease at a more treatable stage, often requires less intensive and less expensive treatment. Early-stage interventions can prevent progression to advanced stages that typically involve higher costs for hospitalization, complex therapies, and long-term care, ultimately leading to more efficient use of healthcare resources and, most importantly, to better patient outcomes.

- **Increased workload capacity**. Savings could be enabled with a higher workload capacity by allowing radiologists to maintain the same number of patients while reducing the time required for image reading. By enhancing reading speed and accuracy, the same radiologists can handle an increased volume of medical images, ultimately driving down burnout, labor costs and maximizing productivity.
Also, taking into account that Prostate cancer is the most common type of cancer in men in Norway, the introduction of QP-Prostate could play a crucial role in reducing the number of patients with proven prostate cancer without metastasis and a low-risk profile who receive radical treatment. Although these patients have cancer, if they are assigned a Gleason score of 6, it is typically considered "indolent cancer," meaning it can be managed through active surveillance (such as repeated MRI scans) since the benefits of treating it do not outweigh the risks. This approach has led to a decrease in early radical treatments.

At the Norwegian national level, the proportion of patients receiving such treatments has decreased from 9% in 2018 to 5% in 2023, reflecting positive progress. The use of QP Prostate, can help not only maintain this low percentage but also potentially reduce it further, while also improving overall accuracy in better distinguishing between clinically significant prostate cancer and non-significant cases.

Need for revision of existing national guidelines or preparation of new guidelines

We understand that the National Action Program, which includes guidelines for 'Investigation, Screening for Prostate Cancer (Oslo 2016)', provides the relevant framework for the use of QP-Prostate®. While existing guidelines offer a solid foundation, it appears that updates or additional recommendations regarding the use of a Software and AI-based Medical Device (SaMD) for enhancing the imaging diagnostics in Prostate Cancer would be beneficial.

15. Please provide references to documentation of the health technology's effect and safety (i.e. previous technology assessments). (**Up to 10 key references can be provided**, please do not send attachments in this step of the process):

The multi-case study at Mass General Brigham Hospital, previously mentioned in this document, is currently pending publication; however, it is referenced in the FDA clearance documentation, supporting the clinical validity of the solution.

[1] Mylona, E., Zaridis, D.I., Kalantzopoulos, C.N. *et al.* Optimizing radiomics for prostate cancer diagnosis: feature selection strategies, machine learning classifiers, and MRI sequences. *Insights Imaging* **15**, 265 (2024). https://doi.org/10.1186/s13244-024-01783-9

[2] Yuze Song, Anna M. Dornisch, Robert T. Dess, Daniel J.A. Margolis, Eric P. Weinberg, Tristan Barrett, Mariel Cornell, Richard E. Fan, Mukesh Harisinghani, Sophia C. Kamran, Jeong Hoon Lee, Cynthia Xinran Li, Michael A. Liss, Mirabela Rusu, Jason Santos, Geoffrey A. Sonn, Igor Vidic, Sean A. Woolen, Anders M. Dale, Tyler M. Seibert. Multidisciplinary Consensus Prostate Contours on Magnetic Resonance Imaging: Educational Atlas and Reference Standard for Artificial Intelligence Benchmarking. *International Journal of Radiation Oncology Biology Physics,* (2025). https://doi.org/10.1016/j.ijrobp.2025.03.024

[3] Jimenez-Pastor, A., Lopez-Gonzalez, R., Fos-Guarinos, B., Garcia-Castro, F., Wittenberg, M., Torregrosa-Andrés, A., Marti-Bonmati, L., Garcia-Fontes, M., Duarte, P., Gambini, J. P., Bittencourt, L. K., Kitamura, F. C., Venugopal, V. K., Mahajan, V., Ros, P., Soria-Olivas, E., & Alberich-Bayarri, A. (2023). Automated prostate multi-regional segmentation in magnetic resonance using fully convolutional neural networks. European radiology, 33(7), 5087–5096. https://doi.org/10.1007/s00330-023-09410-9

[4] Rodrigues, N. M., Almeida, J. G., Verde, A. S. C., Gaivão, A. M., Bilreiro, C., Santiago, I., Ip, J., Belião, S., Moreno, R., Matos, C., Vanneschi, L., Tsiknakis, M., Marias, K., Regge, D., Silva, S., ProCAncer-I Consortium, & Papanikolaou, N. (2024). Analysis of domain shift in whole prostate gland, zonal and lesions segmentation and detection, using multicentric retrospective data. *Computers in biology and medicine*, *171*, 108216. https://doi.org/10.1016/j.compbiomed.2024.108216

[5] Rodrigues, Ana Carolina and Almeida, José and Rodrigues, Nuno and Moreno, Raquel and Gaivão, Ana and Bilreiro, Carlos and Santiago, Inês and Ip, Joana and Belião, Sara and Domingues, Inês and Tsiknakis, Manolis and Regge, Daniele and Marias, Kostas and Papanikolaou, Nikolaos, Development and Prospective Validation of a Fully Automatic Bi-Parametric MRI Radiomics Signature to Predict Prostate Cancer Disease Aggressiveness: A Multi-Centric Study Using Over 4000 Patients. http://dx.doi.org/10.2139/ssrn.4671826

[6] Kocak, B., Akinci D'Antonoli, T., Mercaldo, N. *et al.* METhodological RadiomICs Score (METRICS): a quality scoring tool for radiomics research endorsed by EuSoMII. *Insights Imaging* **15**, 8 (2024). https://doi.org/10.1186/s13244-023-01572-w

[7] Sánchez Iglesias, Á., Morillo Macías, V., Picó Peris, A., Fuster-Matanzo, A., Nogué Infante, A., Muelas Soria, R., Bellvís Bataller, F., Domingo Pomar, M., Casillas Meléndez, C., Yébana Huertas, R., & Ferrer Albiach, C. (2023). Prostate Region-Wise Imaging Biomarker Profiles for Risk Stratification and Biochemical Recurrence Prediction. *Cancers*, *15*(16), 4163. https://doi.org/10.3390/cancers15164163

[8] Martí-Bonmatí, L., Alberich-Bayarri, Á., Alberich, L.C., Jiménez, A. (2023). Imaging Biomarkers in Oncology. In: Neri, E., Erba, P.A. (eds) Multimodality Imaging and Intervention in Oncology. Springer, Cham. https://doi.org/10.1007/978-3-031-28524-0_22

[9] Soerensen, S. J. C., Fan, R. E., Seetharaman, A., Chen, L., Shao, W., Bhattacharya, I., Kim, Y. H., Sood, R., Borre, M., Chung, B. I., To'o, K. J., Rusu, M., & Sonn, G. A. (2021). Deep Learning Improves Speed and Accuracy of Prostate Gland Segmentations on Magnetic Resonance Imaging for Targeted Biopsy. *The Journal of urology*, *206*(3), 604–612. https://doi.org/10.1097/JU.0000000000001783

16. Please provide the name of the marketing authorization holder/manufacturer/supplier of the health technology (if applicable/available):

Quibim, S.L.

17. Marketing Authorization Status (MA) or CE-marking: When is MA or CE- marking expected? If possible, provide the time of planned marketing:

QP-Prostate® is a class IIb CE-marked device according to Regulation (EU) 2017/745, Annex IX Chapter I and III (Certificate No. MDR 752989 R000, first issued on 12th October 2022). QP-Prostate® is available in the EU market from 7th December 2022. Quibim meets international regulatory standards and has obtained marketing authorizations for QP-Prostate® in several markets, including the UKCA marking, and FDA 510(k) clearance.

18. Additional relevant information (up to 300 words.)

Quibim operates in full compliance with all applicable regulations, including but not limited to:

- Regulation 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the "GDPR" or "General Data Protection Regulation");
- Spanish Act 3/2018 on the protection of personal data and guarantee of digital rights (the "LOPDgdd");
- The Health Insurance Portability and Accountability Act ("HIPAA"); and
- Other applicable data protection legislation that may amend, supplement or replace the above.

Also, Quibim has obtained the following certifications:

- ISO/IEC 27001:2022 – Information Security Management System (ISMS");
- ISO 13485:2016 and EN ISO 13485:2016 – Quality Management System (QMS);
- National Security Scheme, Medium category (*Esquema Nacional de Seguridad*) in accordance with Spanish Royal Decree 311/2022; and
- Cyber Essentials Scheme.

All Quibim software is developed under our ISO 13485-certified QMS, performing post-market surveillance activities regularly to monitor the safety and performance of all products and services.

As part of our ISMS, all secure development provisions are reviewed annually through independent internal audits, and Quibim periodically reviews the effectiveness of its security measures.

All employees undergo regular data protection training and are subject to strict confidentiality and data secrecy obligations that survive the termination and expiration of their employment relationship with Quibim.

Quibim enters into data processing agreements or equivalent with all contractors, outlining their data protection and security requirements.

In compliance with articles 37, 38, and 39 of the GDPR, Quibim has appointed a Data Protection Officer (dpo@quibim.com) responsible for overseeing and ensuring Quibim's compliance with all relevant data protection legislation.

Further information on data security and privacy is available on Quibim's Trust Hub, which can be accessed publicly on its website.

19. Interests and potential conflicts of interests

Please describe the proposer's relationships or activities that may affect, be influenced by, or be perceived by others to be important for further management of the health technology that is proposed assessed. (E.g. proposer has financial interests in the matter. Proposer has or has had assignments in connection with the technology or to other actors with interest in the technology)

The proposer is an employee of the Business Development Team at Quibim S.L., the provider of QP-Prostate®. The proposer has no conflicts of interests that may affect the health technology assessment