1. Device identification and general information

1.1. Device trade name(s)

P-score Web Service (PWS)

1.2. Manufacturer's name and address

Prostatype Genomics AB
Augustendalsvägen 20
131 52 Nacka Strand
SWEDEN

1.3. Manufacturer's single registration number (SRN)

SE-MF-000013349

1.4. Basic UDI-DI

735008646PG000424

1.5. European Medical Device Nomenclature (EMDN) description / text

- EMDN level 3 code: W0201 - Chemistry / Immunochemistry Instruments
- Most granular level: W0201030192 - MIXED PANEL MULTIPARAMETER ANALYSERS - IVD MEDICAL DEVICE SOFTWARE

1.6. Risk class of device

Class C (rule 3h)

1.7. Year when the device was first CE-marked under Regulation (EU) 2017/746 covering the device

2024

1.8. Authorised representative if applicable; name and the SRN

Not Applicable.

1.9. NB's name (the NB that will validate the SSP) and the NB's single identification number

TÜV SÜD: NB 0123

2. Intended purpose and other indications

2.1. Intended purpose (elements in Annex II 1.1 (c))

P-score Web Service (PWS) is an In Vitro Diagnostic (IVD) medical device software intended to be used to calculate a P-score, based on gene expression data from the Prostatype RT-qPCR kit together with other established clinical data (PSA, Gleason score, & Tumor stage). P-score provide additional prognostic information to guide treatment decisions of patients who have been diagnosed with localized or metastasis-free prostate cancer. The P-score results shall be used in conjunction with other clinical tools for prognostic evaluation, and not used as an independent predictor. The Prostatype RT-qPCR kit and the P-score are not intended to be used as diagnosis of prostate cancer.

2.2. Indication(s) and target population(s)

Indications:
Localized metastasis free Prostate Cancer

Intended patient population:
P-score Web Service (PWS) is intended for the prognostic evaluation by physicians as a decision support tool for evaluating treatment options in patients over the age of 18 with localized prostate cancer.

2.3. Indication whether it is a device for near-patient testing and/or a companion diagnostic

The device is not for near-patient testing and/or a companion diagnostic.

2.4. Limitations and/or contra-indications (e.g. relevant interferences, cross-reactions)

Limitations: Men over the age of 18 years
Contra-indications: Patients with metastasis at diagnosis.

3. Device description

3.1. Description of the device, including the conditions to use the device (e.g. laboratory, near-patient testing)

P-score Web Service (PWS) is a cloud based medical device software that calculates a risk score, P-score, based on the expression levels of three genes (IGFBP3, F3, and VGLL3) relative to the expression level of GAPDH, from the Prostatype RT-qPCR kit, and other established clinical data (PSA, Gleason score, & Tumor stage). The P-score provide prognostic insights to guide treatment decisions of patients diagnosed with localized prostate cancer.

The principal of operation and the mathematical approach
PWS calculates a risk score (P-score) to predict the risk of death from prostate cancer. P-score is a point-based scoring system based on a Fine-Gray competing risk model. The model was used to establish the P-score based on the three-gene signature combined with PSA, Gleason grade, & Tumor stage at diagnosis.

3.2. In case the device is a kit, description of the components (including regulatory status of components, for example, IVDs, medical devices and any Basic UDI-DIs)

P-score web service (PWS) is not a kit.

3.3. A reference to previous generation(s) or variants if such exists, and a description of the differences

P-score web service (PWS) is Product Model number 2.
PWS had an older generation called CPMA which was a stationary software that needed to be installed in the computer whereas PWS is a cloud-based solution.

3.4. Description of any accessories which are intended to be used in combination with the device

The device has no accessories.

3.5. Description of any other devices and products which are intended to be used in combination with the device

Data from Prostatype® RTqPCR Kit and clinical data for PSA, Gleason grade, & Tumor stage is needed as input when using P-score web service (PWS).

4. Reference to any harmonised standards and CS applied

Common specifications

IEC-62304:2006 + AMD1:2015	Medical device software – Software life cycle processes + Amendment 1 - Medical device software - Software life cycle processes
Harmonised standards	
EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019, EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

5. Risks and warnings

5.1. Residual risks and undesirable effects

The overall residual risk associated with the P-score Web Service (PWS) is considered acceptable.
Residual risks are primarily related to potential incorrect or incomplete data input and cybersecurity or data integrity aspects inherent to software-based systems. Measures such as input validation, system controls, and user guidance have been implemented to mitigate these risks.
Post-market surveillance and risk management activities confirm that the identified residual risks remain low and are outweighed by the clinical benefits of the device.

5.2. Warnings and precautions

The P-score Web Service (PWS) is intended for use by trained healthcare professionals.
To ensure reliable results:

- Only verified gene expression data from the Prostatype® RT-qPCR Kit and accurate clinical parameters shall be used as input.
- Incorrect or incomplete input data may result in inaccurate risk estimation.
- The P-score shall be interpreted in conjunction with other clinical information and not used as a standalone basis for diagnosis or treatment decisions.

- Users should ensure appropriate data handling and cybersecurity practices when accessing the web-based application.

Failure to follow these precautions may lead to incorrect interpretation of results.

5.3. Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN), if applicable

There has not been any field safety corrective action associated with the device.

6. Summary of performance evaluation and post-market performance follow-up (PMPF)

6.1. Summary of scientific validity of the device

The scientific validity of the P-score Web Service is based on the established association between the P-score and clinically relevant outcomes in prostate cancer, particularly prostate cancer-specific mortality.
The P-score integrates gene expression biomarkers (VGLL3, IGFBP3, and F3) with established clinical parameters (PSA, Gleason score, and clinical T-stage), reflecting current state-of-the-art approaches in multivariable prognostic modelling. This combined approach has been shown to improve risk stratification compared with clinical parameters alone.
Internal and external evidence, including retrospective cohort studies and scientific literature, demonstrate that the P-score provides clinically meaningful prognostic information and is associated with long-term outcomes in localized prostate cancer.
Overall, the scientific validity of the device is considered established.

6.2. Summary of performance data from the equivalent device, if applicable

Not an equivalent device.

6.3. Summary of performance data from conducted studies of the device prior to CE marking

Clinical performance of the P-score Web Service has been demonstrated in multiple retrospective studies using prostate biopsy samples.
In a key study including 591 patients, the P-score showed a strong association with prostate cancer-specific mortality, with higher P-scores associated with an increased risk of prostate cancer-specific mortality. The model stratified patients into risk groups with significantly different outcomes and demonstrated improved prognostic performance compared with established clinical risk models such as D'Amico and NCCN.
Additional studies confirmed that the P-score provides reliable risk stratification,

correlates with adverse pathological features, and remains predictive across different cohorts and clinical settings.
These data demonstrate that the device provides clinically meaningful and reliable prognostic information for its intended purpose.

6.4. Summary of performance data from other sources, if applicable

Additional performance evidence is derived from scientific literature, independent validation studies, and post-market data.
Recent studies conducted in different populations, including European and Asian cohorts, confirm the robustness and generalisability of the P-score across diverse patient groups. The results consistently demonstrate strong prognostic performance for prostate cancer-specific mortality and other clinically relevant outcomes.
Literature reviews and state-of-the-art assessments support the use of integrated genomic and clinical models for risk stratification in localized prostate cancer.
Post-market data, including user feedback and surveillance activities, have not identified any new safety or performance concerns.

6.5. An overall summary of the performance and safety

The P-score Web Service demonstrates adequate scientific validity, analytical performance, and clinical performance for its intended purpose as a prognostic decision-support tool in prostate cancer.
The device provides reliable risk stratification based on combined molecular and clinical data and supports clinical decision-making when used alongside established clinical tools.
The overall residual risk is considered low and acceptable, and the benefit–risk profile is favourable. The device is not intended to replace clinical judgement or diagnostic procedures but to complement existing clinical assessments.
Post-market data confirm that the device continues to perform as intended, with no identified safety issues.

6.6. Ongoing or planned post-market performance follow-up

Post-market performance follow-up (PMPF) activities are conducted to ensure continued safety, performance, and clinical relevance of the device.
These activities include:

- Monitoring of customer feedback, complaints, and incidents
- Evaluation of clinical performance data and ongoing validation studies
- Regular literature reviews and state-of-the-art assessments
- Surveillance of cybersecurity and software performance

PMPF activities have confirmed that the PWS maintains its expected clinical utility and performance in real-world use, with no new risks identified.
New validation studies are continuously reviewed and incorporated into the performance evaluation as appropriate.

7. Metrological traceability of assigned values

7.1. Explanation of the unit of measurement, if applicable

No metrological assigned values are used in the products.

7.2. Identification of applied reference materials and/or reference measurement procedures of higher order used by the manufacturer for the calibration of the device

The P-score Web Service is a software-based device and does not assign quantitative values traceable to reference standards.
The output (P-score) is a calculated risk estimate derived from validated input parameters, including gene expression data and clinical variables.
Performance of the device is ensured through verification and validation of the underlying algorithm, input data requirements, and predefined acceptance criteria.

8. Suggested profile and training for users

The P-score Web Service is intended for use by trained healthcare professionals, including physicians and laboratory personnel involved in prostate cancer management.
Users shall have:

- Knowledge of prostate cancer diagnosis and treatment
- Understanding of relevant clinical parameters (e.g. PSA, Gleason score, T-stage)
- Training in the correct use and interpretation of the P-score

Appropriate training is provided by Prostatype Genomics to ensure correct use of the system and interpretation of results.

9. Revision history

SSP version	Date	Change description	NB validated
701002A	2022-11-25	Initial version	Yes

SSP-1 v1	2024-02-05	Transfer to IVDR-compliant QMS; editorial updates	Yes
SSP-1 v2	2024-07-12	Addition of performance information	Yes
SSP-1 v3	2024-09-26	Confidentiality adjustments and minor administrative updates	No
SSP-1 v4	2024-11-29	Alignment with MDCG guidance and editorial updates	No
SSP-1 v5	2025-01-15	Minor administrative updates	No
SSP-2 v1	2026-06-10	Separated from the SSP for Prostatype RT-qPCR kit. Restructured and simplified for public SSP publication and alignment with IVDR requirements.	No