1. Device identification and general information

1.1. Device trade name(s)

Prostatype® RTqPCR Kit

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

735008646PG000526

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

- EMDN level 3 code: W0106 - Genetic testing
- Most granular level: W010699 - genetic testing other

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))

Prostatype RT-qPCR kit is an In Vitro Diagnostic (IVD) medical device analyzing the mRNA expression levels of three embryonal cancer stem cell genes in existing biopsies of patients who have been diagnosed with localized or metastasis-free prostate cancer. The kit is to be used in conjunction with P-score Web Service (PWS), to provide additional prognostic information to guide treatment decisions. 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: Prostatype RT-qPCR kit is intended for the prognostic evaluation by physicians as a decision support tool for evaluating treatment options for 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)

Prostatype RT-qPCR kit is an In Vitro Diagnostic (IVD) medical device including a PCR test, which utilizes one-step reverse transcription quantitative PCR (RT-qPCR) for the assessment of the mRNA expression levels of three genes (IGFBP3, F3, and VGLL3) relative to the expression level of GAPDH in total RNA extracted from formalin-fixed paraffin-embedded (FFPE) human prostate cancer tissue.

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)

Prostatype RT-qPCR kit consists of various reagents. Only the Prostatype kit is CE marked not the raw materials included in the kit. All the reagents go through incoming quality control check and must meet required criteria to be incorporated in the kit.

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

Prostatype RT-qPCR kit is Product Model number 1.

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

Need RT-qPCR instrument, FFPE RNA extraction kits and general laboratory accessories are required. Detailed information can be found in the kit's instructions for use.

4. Reference to any harmonised standards and CS applied

Common specifications	
None	*None*
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 posed by Prostatype® RTqPCR Kit has been demonstrated to be acceptable.

5.2. Warnings and precautions

The Prostatype® RT-qPCR Kit is intended for use in professional laboratory settings by trained personnel. Standard laboratory safety procedures shall be followed. To minimize contamination and ensure reliable results:

- Use appropriate protective equipment (e.g. laboratory coat and gloves).
- Prevent cross-contamination by separating pre-PCR and post-PCR activities and by using dedicated work areas and equipment.
- Use only validated protocols and follow the Instructions for Use (IFU) carefully.
- Ensure adequate sample quality and tumor content, as insufficient or degraded RNA may lead to invalid or unreliable results.

Failure to follow these precautions may lead to invalid test 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

Scientific validity of the Prostatype® RT-qPCR Kit is based on the established association between the expression levels of the genes IGFBP3, F3, and VGLL3 and prostate cancer prognosis. These biomarkers have been shown, through published literature and internal studies, to be involved in key biological processes such as tumor growth, progression, and metastasis. The three-gene signature has been demonstrated to correlate with prostate cancer severity and patient outcomes, including prostate cancer-specific mortality.
Current clinical guidelines and scientific literature support the use of gene expression–based biomarkers as prognostic tools in localized prostate cancer. The selected genes and their combined use are consistent with the state of the art for genomic classifiers used to support risk stratification.

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 Prostatype® RT-qPCR Kit has been demonstrated in retrospective studies using prostate biopsy samples. These studies showed that the three-gene expression signature can stratify patients into distinct risk groups with significantly different survival outcomes.
In one study, patients classified as high-, intermediate-, and low-risk showed clear differences in overall survival. In another study, adding gene expression data to standard clinical parameters improved the prediction of patient outcomes compared to clinical parameters alone.
Analytical performance studies demonstrated that the assay provides reliable and reproducible measurements of gene expression, with high sensitivity, specificity, precision, and robustness across different laboratories and operators.

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

Additional performance evidence is derived from published scientific literature and post-market data. External studies and literature reviews confirm the prognostic relevance of the biomarkers IGFBP3, F3, and VGLL3 in prostate cancer.
Post-market surveillance data, including internal quality control monitoring and customer feedback, support continued analytical performance and clinical utility of the device. No significant safety or performance concerns have been identified in real-world use.

6.5. An overall summary of the performance and safety

The Prostatype® RT-qPCR Kit demonstrates adequate analytical and clinical performance for its intended purpose as a prognostic support tool in prostate cancer. The assay provides reliable measurement of gene expression and contributes clinically relevant information for risk stratification.
The overall residual risk associated with the device is considered acceptable and is outweighed by its clinical benefit. The test is intended to support, but not replace, clinical decision-making and should be used in conjunction with other clinical information.
Post-market data confirm that the device performs as intended, with no identified safety issues. The benefit–risk profile remains favorable.

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

Post-market performance follow-up (PMPF) activities are conducted to ensure continued safety and performance of the device in real-world use. These activities include:

- Continuous monitoring of internal quality control data and performance trends
- Review of customer feedback, complaints, and incident reports
- Regular literature reviews to assess scientific validity and state of the art
- Evaluation of clinical performance data and emerging evidence

The results of these activities are reviewed periodically, and updates are made to the performance evaluation and risk management documentation as needed. Current PMPF activities confirm that the device continues to perform as intended and maintains a favorable benefit–risk profile.

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

Performance of the device depends on the acceptance and validity criteria of the positive and negative controls. The values are expression level of the genes in the positive and negative controls. The tested patients reference gene expression also needs to be in a given range.

8. Suggested profile and training for users

The Prostatype RT-qPCR kit is for use in a professional laboratory and only be used by professional laboratory personnel that has been trained and certified by Prostatype Genomics according to the corresponding training document.

9. Revision history

SSP version	Date	Change description	Notified Body validation status
701002A	2022-11-25	Initial version	☒ Validated ☐ Not required
SSP-1 v1	2024-02-05	Transfer to IVDR-compliant QMS; editorial updates	☒ Validated ☐ Not required
SSP-1 v2	2024-07-12	Addition of performance information	☒ Validated ☐ Not required
SSP-1 v3	2024-09-26	Confidentiality adjustments and minor administrative updates	☐ Validated ☒ Not required
SSP-1 v4	2024-11-29	Alignment with MDCG guidance and editorial updates	☐ Validated ☒ Not required
SSP-1 v5	2025-01-15	Minor administrative updates	☐ Validated ☒ Not required
SSP-1 v6	2026-06-10	Restructured and simplified for public SSP publication and alignment with IVDR requirements.	☐ Validated ☒ Not required
SSP-1 v7	2026-09-11	Updated template	☐ Validated ☒ Not required