Presafe®
A DNV GL COMPANY

Quality System Certificate

DANAK
SYSTEM Reg. No. 5007

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 890	Aur1i2105v90f828	2021-05-25	2022-03-27	2016-07-01

This is to certify that the quality system of:

Prostatype Genomics AB
Industrivägen 19
171 48 Solna
Sweden

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Manufacture of IVD reagents and software tools for the evaluation of patients diagnosed with prostate cancer

The certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of Presafe Denmark A/S. Certifications to DS/EN ISO 13485:2012, EN ISO 13485:2012, ISO 13485:2003, DS/EN ISO 13485:2016, EN ISO 13485:2016, ISO 13485:2016, DS/EN ISO 9001: 2015, EN ISO 9001:2015, and ISO 9001:2015 include the requirements of any applicable corrigendum. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.

Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark

Bent Buus
Authorized person

For Presafe Denmark A/S

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Sites covered by the certificate:

Prostatype Genomics AB
Industrivägen 19
171 48 Solna
Sweden

Prostatype Genomics AB
Banvaktsvägen 22
171 48 Solna
Sweden