



Quality System Certificate

Certificate Number: DGM – 890

This is to certify that the quality system of:

Chundsell Medicals AB

Industrivägen 19
171 48 Solna
Sweden

fulfills the requirements in:

DS/EN ISO 13485:2012

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 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the applicable corrigenda. The quality system certificate is issued pursuant to Presafe Denmark A/S' terms and conditions for the certification of quality systems for medical devices.


Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Date of issue: 2017-02-21
Expires: 2019-07-01
Initial date of issue: 2016-07-01
Reference: aur1i1701v30f828

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark



The following sites are covered by the certificate:

With the following sites in Sweden:

Chundsell Medicals AB
Industrivägen 19
171 48 Solna
Sweden

Chundsell Medicals AB
Banvaktsvägen 22
SE-171 AB Solna
Sweden

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