

This is to certify that the quality system of:

Statens Serum Institut
Artillerivej 5
2300 Copenhagen S
Denmark

fulfills the requirements in:

DS/EN ISO 9001:2008 and
DS/EN ISO 13485:2012

The certificate covers the following activities:

Development, production and sale of in vitro-diagnostics
and animal blood products

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: 2016-04-12
Expires: 2018-09-15
Initial date of issue: 2008-09-24
Reference: auri1602v101f032

Presafe Denmark A/S

Tuborg Parkvej 8
2900 Hellerup
Denmark

Additional sites covered by the certificate:

**SSI Diagnostika
Herredsvejen 2
3400 Hillerød**

**Hvidesten
Frederiksborgvej 71
3450 Allerød**

Certificate number: DGM – 645.1
Certificate type: Quality System Certificate

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