

## Quality System Certificate

DGM-645.3

This is to certify that the quality system of

**Statens Serum Institut**  
**Artillerivej 5, 2300 København S**  
**SSI Diagnostika, Herredsvejen 2, 3400 Hillerød**  
**Hvidesten, Frederiksborgvej 71, 3450 Allerød**  
**Denmark**

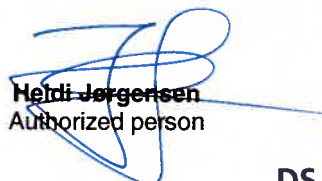
fulfils the requirements in

**DS/EN ISO 9001:2008 and**  
**DS/EN ISO 13485:2003**

The scope of the certificate is:

**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 DS Certificering A/S. Certifications to DS/EN ISO 13485:2003, EN ISO 13485:2003, ISO 13485:2003, DS/EN ISO 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the valid corrigenda. The quality system certificate is issued pursuant to the DS Certificering A/S rules for the certification of quality systems for medical devices.

  
**Heidi Jørgensen**  
Authorized person

Valid from: 2010-05-17  
Valid until: 2013-05-17  
Initial date of issue: 2008-09-24  
Reference: Aur1i1002v40f032

**DS Certificering A/S**

*Notified Body, Identification No. 0543*  
Kollegievej 6, DK-2920 Charlottenlund, Denmark