Quality System Certificate

DANAK SYSTEM Reg. No. 5007

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 893	aur1i1901v60f841	2019-03-06	2022-03-06	2016-09-27

This is to certify that the quality system of:

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Danmark

fulfills the requirements in:

DS/EN ISO 13485:2016

The certificate covers the following activities:

Development, Manufacturing, Sales and Distribution of in vitro-diagnostica and blood products from animals

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

Heidi Jørgensen
Authorized person

For Presafe Denmark A/S

Quality System Certificate

Certificate No.:	Reference:	Date of issue:	Valid Until:	Initial date of issue:
DGM – 893	**aur1i1901v60f841**	**2019-03-DD**	**2022-03-DD**	**2016-09-27**

Additional site(s) covered by the certificate:

Hvidesten
Frederiksborgvej 71
3450 Allerød
Danmark