



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
C700377

Initial certification date:
2026-02-19

Expiry Date:
2029-02-20

This is to certify that the management system of

SSI Diagnostica A/S

Herredsvejen 2, 3400 Hillerød, Denmark

F008527

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 820

Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

This certificate is valid for the following scope:

The design and development, manufacture and servicing of in-vitro diagnostic analyzers/software, in-vitro diagnostic medical devices, in-vitro diagnostic reagents, in-vitro diagnostic test kits used in the diagnosis, management, detection of autoimmune status, blood analytes, blood components, compatibility testing, disease status, immune status, immunological typing.

Place
Høvik

Effective Date:
2026-02-19



DNV is an MDSAP
Recognized Auditing Organization



For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or in the link, <https://certificatechecker.dnv.com/>, with the certificate number/manufacturer name.



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Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
SSI Diagnostica A/S F008527	Herredsvejen 2, 3400 Hillerød Denmark	The design and development, manufacture and servicing of in-vitro diagnostic analyzers/software, in-vitro diagnostic medical devices, in-vitro diagnostic reagents, in-vitro diagnostic test kits used in the diagnosis, management, detection of autoimmune status, blood analytes, blood components, compatibility testing, disease status, immune status, immunological typing.
SSI Diagnostica A/S F008527	Frederiksborgvej 71 3450 Allerød Denmark	Manufacturing of blood components.

