



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Nordic Biomarker AB Vildmannavägen 1 Umeå 903 47 Sweden

Holds Certificate Number:

MD 786256

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

> Design, development, manufacture, contract manufacture, and sale of in-vitro diagnostic reagents, calibrators, controls, and accessories for use in haemostasis diagnostics.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2023-07-21 Latest Revision Date: 2024-01-30

Effective Date: 2024-03-06 Expiry Date: 2027-03-05

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Certificate No: MD 786256

Sweden

582 13 Sweden

Location Registered Activities

Nordic Biomarker AB
Vildmannavägen 1
Design, development, manufacture, contract manufacture, and sale of in- vitro diagnostic reagents, calibrators, controls,

Umeå and accessories for use in haemostasis diagnostics.

903 47

Nordic Biomarker AB

Ebbegatan 9

Linköping

Design, development, manufacture, and contract
manufacture of in- vitro diagnostic reagents, calibrators,
controls, and accessories for use in haemostasis diagnostics.



Original Registration Date: 2023-07-21 Effective Date: 2024-03-06 Latest Revision Date: 2024-01-30 Expiry Date: 2027-03-05

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