



Certificate of Registration

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

This is to certify that:

Euro Diagnostica AB Lundavägen 151 MALMÖ SE-212 24 Sweden

Holds Certificate Number:

MD 582127

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

The design and development, manufacture and distribution of RIA, ELISA and lateral flow invitro diagnostic devices for use in diagnosis and monitoring of autoimmunity, gastroenterology, endocrinology, oncology and complement activity.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-02-15 Effective Date: 2018-08-05 Latest Revision Date: 2018-07-30 Expiry Date: 2021-08-04

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>. Printed copies can be validated at www.bsigroup.com/ClientDirectory