

# 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 in-vitro 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

Latest Revision Date: 2018-07-30

Effective Date: 2018-08-05

Expiry Date: 2021-08-04

Page: 1 of 1



003

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