

# Certificate of Registration

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

This is to certify that:

Diagnotix BV  
De Plassen 4  
9902 SE  
Appingedam  
The Netherlands

Holds Certificate Number:

**MD 724530**

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

Manufacture and distribution of clinical in-vitro diagnostic reagents and kits for LC-MS, (U)HPLC and spectrophotometric assays, to be used as medical tests for the determination of specific analytes by clinical laboratories.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-02-04

Latest Revision Date: 2024-01-18

Effective Date: 2024-02-04

Expiry Date: 2027-02-03

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