

Certificate of Registration

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

This is to certify that:

Blackhills Diagnostic Resources S.L.U.
Camino del Pílon, 86
Casa 7
Zaragoza
50011
Spain

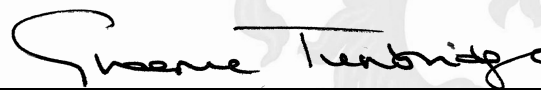
Holds Certificate Number:

MD 573003

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, production and distribution of nucleic acid testing in-vitro diagnostic reagents for immunology and genetic disorders

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2011-09-20

Latest Revision Date: 2023-08-24

Effective Date: 2023-09-20

Expiry Date: 2026-09-19

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