

# 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 Pilón, 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 Global Regulatory & Quality

Original Registration Date: 2011-09-20

Latest Revision Date: 2024-09-05

Effective Date: 2023-09-20

Expiry Date: 2026-09-19

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Certificate No: MD 573003

Location

Blackhills Diagnostic Resources, S.L.U  
c.º Pilón, 86, casa 7  
Zaragoza  
50011  
Spain

Registered Activities

Design, development and quality control.

Blackhills Diagnostic Resources S.L.U.  
Av. Diagonal Plaza 40  
Zaragoza  
50197  
Spain

Manufacturing, administration, sales, technical support, and quality.



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