

# Certificate of Registration

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

This is to certify that:

NimaGen B.V.  
Hogelandseweg 88  
6545 AB Nijmegen  
The Netherlands

Holds Certificate Number:

MD 711483

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 in vitro diagnostic reagents and kits for molecular diagnostics, including detection of infectious diseases, inherited disorders, and human genetic variations.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-07-09

Latest Revision Date: 2025-06-09

Effective Date: 2025-07-09

Expiry Date: 2028-07-08

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