By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Genmark Diagnostics Inc
5964 La Place Ct
Carlsbad
California
92008
USA

Holds Certificate Number: FM 702927

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

Design, manufacturing and distribution of in vitro molecular diagnostic systems in the areas of genetic diseases, pharmacogenetics, infectious diseases, and oncology.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2012-09-21
Latest Revision Date: 2026-07-06

Effective Date: 2025-08-22
Expiry Date: 2028-08-01

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Information and Contact:
BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands | Tel: +31 20 3460 780
BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.
America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.

Certificate No: FM 702927

Location	Registered Activities
Genmark Diagnostics Inc 5964 La Place Ct Carlsbad California 92008 USA	Design, manufacturing and distribution of in vitro molecular diagnostic systems in the areas of genetic diseases, pharmacogenetics, infectious diseases, and oncology.
Genmark Diagnostics Inc 2210 Faraday Avenue Carlsbad California 92008 USA	Manufacture of in vitro molecular diagnostic systems in the areas of genetic diseases, pharmacogenetics, infectious diseases, and oncology.
Genmark Diagnostics Inc 6221 el Camino Real Carlsbad California 92009 USA	Manufacture of in vitro molecular diagnostic systems in the areas of genetic diseases, pharmacogenetics, infectious diseases, and oncology.
Genmark Diagnostics Inc 11010 Torreyana Road San Diego California 92121 USA	Design and development.
Genmark Diagnostics Inc 5840 El Camino Real Suite 111 Carlsbad California 92008 USA	Manufacturing of in vitro molecular diagnostics systems in areas of genetic diseases, pharmacogenetics, infectious diseases, and oncology.

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