

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Remel, Inc.
12076 Santa Fe Trail Drive
Lenexa
Kansas
66215
USA

Holds Certificate No:

FM 586933

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

Design, development, manufacture, and distribution of in- vitro diagnostic analyzers/software, in-vitro diagnostic medical devices, in-vitro diagnostic reagents, and in-vitro diagnostic test kits used in the diagnosis, management, and detection of coagulation, disease status, immune status, pregnancy testing, sexually transmissible agents, transmissible agents, and immunological typing including laboratory in-vitro diagnostic devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2012-05-07

Latest Revision Date: 2021-04-09

Effective Date: 2019-12-11

Expiry Date: 2022-12-10



Page: 1 of 2

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Certificate No: **FM 586933**

Location	Registered Activities
Remel, Inc. 12076 Santa Fe Trail Drive Lenexa Kansas 66215 USA	Planning, engineering, maintenance, quality control, manufacturing.
Remel, Inc. 12150 Santa Fe Trail Drive Lenexa Kansas 66215 USA	Order entry, customer service, technical service, contracts, marketing, sales, product management, finance, human resources.
Remel, Inc. 12230 Santa Fe Trail Drive Lenexa Kansas 66215 USA	Powder and organism manufacture, quality, regulatory, quality control.
Remel, Inc. 17501 W. 98th Street, Pillars 30-60 Lenexa Kansas 66219-1737 USA	Storage and distribution facility, kit packaging.
Remel, Inc. 17000 W 116th St Lenexa Kansas 66219 USA	Manufacturing and Quality control of Viral Transport Media, Distribution Storage, Maintenance, Planning, Human Resources.

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Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.