

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 Number: **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 (including installation and service), 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2012-05-07

Latest Revision Date: 2022-12-06

Effective Date: 2022-12-11

Expiry Date: 2025-12-10

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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 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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This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.

An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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