

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 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.

This certificate is traceable to the company's original registration certificate number CERT-0049796 dated March 20, 2009 and issued by SAI Global.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2012-05-07

Effective Date: 2017-06-08

Expiry Date: 2019-02-28



**CMDCAS
Recognized
Registrar**



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...making excellence a habit.™

Certificate No: **FM 586933**

Location	Registered Activities
Remel, Inc. 12076 Santa Fe Trail Drive Lenexa Kansas 66215 USA	Quality Management System for the 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.
Remel, Inc. 2797 Peterson Place Norcross Georgia 30071 USA	Design support and manufacture of in-vitro diagnostic medical devices, in-vitro diagnostic reagents, and in-vitro diagnostic test kits used in the diagnosis, management, and detection of disease status, immune status, sexually transmissible agents, transmissible agents, and laboratory in-vitro diagnostic devices.
Remel, Inc. 12150 Santa Fe Trail Drive Lenexa Kansas 66215 USA	Quality Management System for the 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.
Remel, Inc. 12230 Santa Fe Trail Drive Lexena Kansas 66215 USA	Quality Management System for the 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.

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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](http://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.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA

A Member of the BSI Group of Companies.

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Location	Registered Activities
Remel, Inc. 17501 W. 98th Street, Pillars 30-60 Lenexa Kansas 66219-1737 USA	Quality Management System for the 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.
Remel Inc. 13595 NW 2300 Road Garnett Kansas 66032 USA	Quality Management System for the 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.

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