



By Royal Charter

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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2012-05-07

Latest Revision Date: 2019-12-11

Effective Date: 2019-12-11

Expiry Date: 2022-12-10

Page: 1 of 3



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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.

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.
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.

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.

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Location

Remel Inc.
13595 NW 2300 Road
Garnett
Kansas
66032
USA

Registered Activities

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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