bsi.

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

...making excellence a habit.

Digitally signed by Lazari Cristina
Date: 2022.07.22 16:09:57 EEST
Reason: MoldSign Signature
Location: Moldova

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	Registered Activities
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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