

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

Facility ID Number: F001452

Holds Certificate No:

MDSAP 698726

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations - Part 1 - SOR 98/282

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-12-11

Effective Date: 2022-12-11

Expiry Date: 2025-12-10



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 698726**

Registered 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.



Original Registration Date: 2019-12-11 Effective Date: 2022-12-11

Expiry Date: 2025-12-10

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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](#). 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: **MDSAP 698726**

Location	Registered Activities
Remel, Inc. 12076 Santa Fe Trail Drive Lenexa Kansas 66215 USA Facility ID Number: F001452	Planning, engineering, maintenance, quality control, manufacturing
Remel, Inc. 12150 Santa Fe Trail Drive Lenexa Kansas 66215 USA Facility ID Number: F001452	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 Facility ID Number: F001452	Powder manufacture, quality, regulatory, quality control.
Remel, Inc. 17501 W. 98th Street, Pillars 30-60 Lenexa Kansas 66219-1737 USA Facility ID Number: F001452	Storage and distribution facility, kit packaging.
Remel, Inc. 17000 W 116th St Lenexa Kansas 66219 USA Facility ID Number: F001452	Manufacturing and Quality control of Viral Transport Media, Distribution Storage, Maintenance, Planning, Human Resources.

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