



## Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Remel, Inc. 1 Thermo Fisher Way Oakwood Village Ohio 44146 USA

Holds Certificate No:

FM 610681

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacturing, installation, distribution and service of in vitro diagnostic reagent systems including instruments and associated software, used in a research and clinical environments for the identification of microorganisms and susceptibility testing of Mycobacteria.

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For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2014-01-31 Latest Revision Date: 2019-12-23





Effective Date: 2020-02-24 Expiry Date: 2023-02-23

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.