

# 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.



For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2014-01-31

Latest Revision Date: 2018-12-03

Effective Date: 2019-01-01

Expiry Date: 2020-02-23

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