



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

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 13485:2003 for the following scope:

Design, validation, installation, service, and repair of in-vitro diagnostic medical devices used in the detection and identification of microorganisms, and in the susceptibility testing of mycobacteria. The design, validation, and manufacture of software. The installation of the software on to computers associated with medical devices. Design development, manufacture and distribution of diagnostic products for research use only.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 01/31/2014

Latest Revision Date: 02/24/2017

Effective Date: 02/26/2017

Expiry Date: 02/28/2019

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