



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 Number: 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2014-01-31

Latest Revision Date: 2022-12-01

Effective Date: 2023-02-24

Expiry Date: 2026-02-23

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