

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Remel Europe Limited
Remel House
Clipper Boulevard West
Crossways
Dartford
Kent
DA2 6PT
United Kingdom

Holds Certificate Number:

MD 76389

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

The design, manufacture and distribution of in-vitro diagnostic test kits, used in the diagnosis of disease status, coagulation and transmissible agents.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2003-09-18

Latest Revision Date: 2024-10-10

Effective Date: 2024-11-30

Expiry Date: 2027-11-29



Page: 1 of 1

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