

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

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 13485:2003 & EN ISO 13485:2012 for the following scope:

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

For and on behalf of BSI:



Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 18/09/2003

Latest Revision Date: 12/04/2017

Effective Date: 01/05/2017

Expiry Date: 28/02/2019

Page: 1 of 1



003

...making excellence a habit.™