



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

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...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory