



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, autoimmune status, coagulation, and transmissible agents.

For and on behalf of BSI:

JM SI

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2003-09-18 Latest Revision Date: 2018-11-30



Effective Date: 2018-11-30

Expiry Date: 2021-11-29

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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

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