Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

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

DUNS Number: 23-260-0853

Holds certificate No: **MDSAP 692425**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure [if design controls are part of the certification]; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1- SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

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:

Stewart Brain, Head of Compliance & Risk – Medical Devices

Original Registration Date: 2019-03-22 Effective Date: 2019-03-22 Expiry date: 2021-11-29

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BSI Group America Inc. is an MDSAP authorized auditing organization