

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Facility ID Number: F000376

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; 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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-03-22

Effective Date: 2021-11-30

Expiry Date: 2024-11-29



BSI Group America Inc. is an MDSAP authorized auditing organization

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# Certificate of Registration

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

This is to certify that:

Oxoid Limited  
Wade Road  
Basingstoke  
RG24 8PW  
United Kingdom

Holds Certificate Number:

**MD 80930**

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, development and manufacture of laboratory diagnostics for the detection, isolation, identification and susceptibility testing of micro-organisms.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2004-01-26

Latest Revision Date: 2021-11-12

Effective Date: 2021-11-15

Expiry Date: 2024-11-14

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Certificate No: **MD 80930**

Location	Registered Activities
Oxoid Limited Wade Road Basingstoke RG24 8PW United Kingdom	The design, development and manufacture of laboratory diagnostics for the detection, isolation, identification and susceptibility testing of micro-organisms.
Oxoid Limited Unit B, Logisitics City Brunel Road Houndmills Industrial Estate Basingstoke RG21 6XL United Kingdom	Warehousing and Customer services



Original Registration Date: 2004-01-26

Latest Revision Date: 2021-11-12

Effective Date: 2021-11-15

Expiry Date: 2024-11-14