



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Oxoid Limited

Wade Road Basingstoke Hampshire RG24 8PW United Kingdom

Facility ID Number: F000355

Holds Certificate No: MDSAP 692787

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full

Quality Assurance Procedure

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

Effective Date: 2023-01-20

For and on behalf of BSI:

Original Registration Date: 2019-03-20

Graeme Tunbridge, Senior Vice President Medical Devices

Page: 1 of 2

Expiry Date: 2024-11-14

MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization ....making excellence a habit.™

Certificate No: MDSAP 692787

## Location Registered Activities

Oxoid Limited Wade Road Basingstoke Hampshire RG24 8PW

United Kingdom

Facility ID Number: F000355

Oxoid Limited
Unit B, Logisitics City
Brunel Road

Houndmills Industrial Estate

Basingstoke Hampshire RG21 6XL United Kingdom

Facility ID Number: F000355

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

The distribution of laboratory diagnostics for the detection, isolation, identification and susceptibility testing of microorganisms.



Original Registration Date: 2019-03-20 Effective Date: 2023-01-20 Expiry Date: 2024-11-14

Page: 2 of 2