

# 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. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-03-20

Effective Date: 2023-11-21

Expiry Date: 2024-11-14



BSI Group America Inc. is an MDSAP recognised auditing organization

Certificate No: **MDSAP 692787**

Location

Oxoid Limited  
Wade Road  
Basingstoke  
Hampshire  
RG24 8PW  
United Kingdom  
Facility ID Number: F000355

Registered Activities

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

Oxoid Limited  
Unit B, Logistics City  
Brunel Road  
Houndmills Industrial Estate  
Basingstoke  
Hampshire  
RG21 6XL  
United Kingdom  
Facility ID Number: F000355

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



Original Registration Date: 2019-03-20

Effective Date: 2023-11-21

Expiry Date: 2024-11-14

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](https://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.