

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Maine Molecular Quality Controls, Inc.  
23 Mill Brook Rd  
Saco  
Maine  
04072  
USA

Facility ID Number: F006877

Holds Certificate No:

**MDSAP 792018**

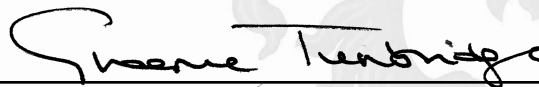
The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture and distribution of quality control materials used to monitor the performance of in vitro diagnostic assays for the diagnosis and management of cancer, infectious diseases and genetics.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-02-12

Effective Date: 2025-02-12

Expiry Date: 2027-12-10



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

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