



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Life Technologies

part of Thermo Fisher Scientific

3175 Staley Road Grand Island New York 14072 USA

Facility ID Number: F003407

Holds Certificate No: MDSAP 705469

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, manufacture and distribution of liquid and powder tissue culture media, sera, reagents and distribution of biochemicals.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2020-03-31 Effective Date: 2023-03-31 Expiry Date: 2026-03-30

Page: 1 of 2

MEDICAL DEVICE SINGLE AUDIT PROGRAM

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."

Certificate No: **MDSAP 705469** 

## Location Registered Activities

Life Technologies

part of Thermo Fisher Scientific

3175 Staley Road Grand Island New York 14072

Facility ID Number: F003407

Life Technologies part of Thermo Fisher Scientific 2170 Whitehaven Rd Grand Island New York

14072 USA

USA

Facility ID Number: F003407

The design, development, manufacture and distribution of liquid and powder tissue culture media, sera, reagents and distribution of biochemicals.



Original Registration Date: 2020-03-31 Effective Date: 2023-03-31 Expiry Date: 2026-03-30

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. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.