

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. 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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-03-31

Effective Date: 2026-03-31

Expiry Date: 2029-03-30



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 3

...making excellence a habit.™

Certificate No: **MDSAP 705469**

Registered Scope:

The design, development, manufacture and distribution of liquid and powder tissue culture media as in-vitro diagnostic cytogenetics products for hematological disease.

The manufacture of peptones for use as intermediates for in-vitro diagnostic cell culture applications.



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Page: 2 of 3

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.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.
A Member of the BSI Group of Companies.

Certificate No: **MDSAP 705469**

Location

Life Technologies
part of Thermo Fisher Scientific
3175 Staley Road
Grand Island
New York
14072
USA
Facility ID Number: F003407

Registered Activities

The design, development, manufacture and distribution of cell culture media products, including aseptically filled liquids (media, sera, buffers, reagents) and dry medias (powder and Advanced Granulation Technology).

Life Technologies
part of Thermo Fisher Scientific
2170 Whitehaven Rd
Grand Island
New York
14072
USA
Facility ID Number: F003407

Product laboratory testing - Mycoplasma.



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Page: 3 of 3

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