

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

LifeGlobal Group, LLC
Also doing business as LifeGlobal
393 Soundview Road
Guilford
Connecticut
06437
USA

Facility ID Number: F000264

Holds Certificate No:

MDSAP 685801

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 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

Design, development, manufacture and distribution of products for use in the assisted reproductive and in-vitro fertilization marketplace, including Aspiration Devices, Air Filtration Systems, Culture Media and Labware.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-02-20

Effective Date: 2025-02-20

Expiry Date: 2028-02-19



BSI Group America Inc. is an MDSAP recognised auditing organization

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