By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Analytical Industries, Inc.
2855 Metropolitan Place
Pomona
California
91767
USA

Facility ID Number: F009381

Holds Certificate No: **MDSAP 852054**

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: 2026-09-08 Effective Date: 2026-09-08 Expiry Date: 2028-02-03

MDSAP
Medical Device Single Audit Program
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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 852054**

Registered Scope:

Design, manufacture and service of oxygen sensors, oxygen analyzers and oxygen monitors for medical applications.

Transfer from Intertek
Certificate number: 0222253

Original Registration Date: 2026-09-08 Effective Date: 2026-09-08 Expiry Date: 2028-02-03

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.