MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 096122 0010 Rev. 00

Certificate Holder: **Analytical Industries Inc.**
2855 Metropolitan Place
Pomona CA 91767
USA

Certification Mark:

Scope of Certificate: **Design, Manufacture and Service of Oxygen Sensors, Analyzers and Monitors for Medical Application**

Standard(s): **(ISO 13485:2016)**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW/PMDA. See attachment page for listing of specific regulatory requirements**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **93-142-0624**

Effective Date: **2019-02-04**

Expiry Date: **2022-02-03**

Date of Issue: 2019-02-13

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements:

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

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

Facility Scopes:

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