ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

SCC Accredited CB-MS GCSM Accrédité CCN

America

# CERTIFICATE

## No. QS5 096122 0009 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 9001:2015**

**The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.**

**Report No.:** **72141732**

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

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

Page 1 of 1
**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

US-Letter / 07.17

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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 )
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# CERTIFICATE

**No. QS6 096122 0010 Rev. 00**

**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:**

Design, Manufacture and Service of Oxygen Sensors, Analyzers and Monitors for Medical Application
DUNS No: 93-142-0624


**Date of Issue:** 2019-02-13

( Arie Henkin )
Manager, Certification Body MHS
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Product Service

# EC Certificate

## Full Quality Assurance System

**Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)**
**(Devices in Class IIa, IIb or III)**

**No. G1 16 10 96122 004**

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

**EC-Representative:** **Distribuciones y Respresentaciones Biomedicas Direx, S.L**
Avda. San Pablo, 28. Nave 24
2882 Coslada Madrid
SPAIN

**Product Category(ies):** **Oxygen Sensors, Analyzers and Monitors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:** 72117342

**Valid from:** 2017-02-03
**Valid until:** 2022-02-02

**Date,** 2017-02-03

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123







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TÜV SÜD America

# CERTIFICATE

## No. QS5 096122 0009 Rev. 00

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

**Certification Mark:**

TÜV SÜD ISO 9001

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

**Standard(s):** **ISO 9001:2015**

**The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.**

**Report No.:** **72141732**

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

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

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**Date of Issue:** 2019-02-13

( Arie Henkin )
Manager, Certification Body MHS



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Product Service

## EC Certificate
## Full Quality Assurance System

**Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)**
**(Devices in Class IIa, IIb or III)**

## No. G1 16 10 96122 004

**Facility(ies):**

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





TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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