

CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Analytical Industries Inc.

Main Site: 2855 Metropolitan Place, Pomona CA 91767, USA (FIN F008297)

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6)

Brazil: RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009

Canada: Medical Devices Regulations – Part 1- SOR 98/282

United States: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 (Subparts A to D)

Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68; PMD Act, as applicable

The management system is applicable to:

Design, Manufacture and Service of Oxygen Sensors, Analyzers and Monitors for Medical Application

Organization was certified by another Certification Body before 8/21/2025

Certificate Number:

0222253

Revision Level: 00

Certification Effective Date:

2025-08-21

Certification Expiry Date:

2028-02-03



intertek

Rathin Grover

President, Business Assurance

Intertek Testing Services NA, Inc.
4700 Broadmoor SE, Suite 200
Kentwood, MI, USA, 49512

