

# CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

## Advanced Instruments, LLC

(FIN F000725)

Main Site: Two Technology Way

Norwood, Massachusetts, 02062, United States

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:** Federal Law n. 6360/76; RDC ANVISA n. 16/2013; RDC ANVISA n. 23/2012;  
RDC ANVISA n. 67/2009; RDC ANVISA n. 56/2001

**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

### The management system is applicable to:

*Design, develop, manufacture, installation, support and service of laboratory  
instruments, osmometers, neonatal bilirubin analyzers, reference solutions,  
calibrators, controls, total and direct bilirubin test kits.*

**Certificate Number:**

0081190-01

**Initial Certification Date:**

2018-09-15

**Date of Certification Decision:**

2021-09-14

**Certification Effective Date:**

2021-09-14

**Certification Expiry Date:**

2022-09-14



intertek

**Calin Moldovean**

President, Business Assurance

Intertek Testing Services NA, Inc.  
900 Chelmsford Street  
Lowell, MA, USA 01851

