

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

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