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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: 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

The management system is applicable to:

Design, development, manufacture, installation, and service of laboratory instruments including osmometers, CSF cell counters, and neonatal bilirubin analyzers.

Design, development, and manufacture of reagents, reference solutions, calibrators, controls, total and direct bilirubin test kits.

Certificate Number:
0081190-03

Initial Certification Date:
2018-09-15

Date of Certification Decision:
2024-09-13

Certification Effective Date:
2024-09-14

Certification Expiry Date:
2027-09-14

ISO 13485:2016
CERTIFICATION ™

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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