CERTIFICATE OF REGISTRATION

American Diagnostic Corporation

55 Commerce Drive
Hauppauge
NY 11788 UNITED STATES

REPs Facility ID: F005182

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Manufacture and distribution of digital sphygmomanometers, sphygmomanometer cuffs, sphygmomanometers, stethoscopes, electronic stethoscopes. The distribution of digital thermometers, infrared thermometers, diagnostic instruments, otoscopes, ophthalmoscopes, tuning forks, laryngoscopes, laryngoscope blades, bite sticks, neurological hammers, surgical instruments, valve-mask/face shield CPR products, ring cutters, penlights, disposable airways, tourniquets, shears and pulse oximeters.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Authorized by

Deborah Jennings-Conner
Global Regulatory Director
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

File Number	A28888	Cycle Start Date	March 5, 2021
Certificate Number	3194.210305	Effective Date	March 5, 2021
Initial Issue Date	October 30, 2020	Expiry Date	March 4, 2024

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC.
Certificates may be verified by visiting the Online Certifications Directory on UL.com.

UL REGISTERED FIRM

UL Medical and Regulatory Services UL, LLC is an MDSAP Recognized Auditing Organization

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096 USA

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Additional Regulatory Requirements

Australia:
- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

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

Japan:
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act (,as applicable)

United States:
- 21 CFR 820
- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 – Subparts A to D
- 21 CFR 821 (where applicable)

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