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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Vida Diagnostics, Inc.

(F002543)

Main Site: 2500 Crosspark Road, W250 BioVentures Center

Coralville, Iowa, USA 52241

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)

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:

The design and development, production, installation, and servicing of software manufactured by VIDA diagnostics Inc., used in the diagnosis, documentation, treatment planning, evaluation of treatment response and associated lab services of pulmonary and smoking related diseases via data acquired from various medical modalities.

Certificate Number:
0101904-03

Initial Certification Date:
2020-05-22

Date of Certification Decision:
2023-05-25

Certification Effective Date:
2023-05-25

Certification Expiry Date:
2026-05-21

ISO 13485:2016 CERTIFICATION TM

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM

intertek

Calin Moldovean
President, Business Assurance

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