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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

Gold Standard Diagnostics Corp.

(FIN F000830)

Main Site: 2851 Spafford Street, Davis, CA 95618 United States

Additional Site 1: 620 Cantrill Dr Davis, CA 95618 United States

Additional Site 2: 628 Cantrill Dr Davis, CA 95618 United States

has been registered by Intertek, an MDSAP recognized auditing organization, as conforming to the requirements of:

ISO 13485:2016

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)

The management system is applicable to:

Design and manufacture and distribution of in vitro diagnostic automated platforms and kits for Autoimmune, Infectious Disease, Endocrinology, Microbiology, Oncology and Clinical Chemistry uses.

Additional Site 1 : Manufacturing (Kit Assembly), Incoming Inspection, Warehouse

Additional Site 2 : Manufacturing (Instrumentation), Quality Control

Certificate Number:
0087818

Initial Certification Date:
2019-03-03

Certification Effective Date:
2019-03-03

Certification Expiry Date:
2022-03-02

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Calin Moldovean
President, Business Assurance

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