Certificate

Certificate No.:	MD 1243914-1-1
Manufacturer:	**DRG International., Inc.** 841 Mountain Avenue Springfield NJ 07081 USA
REPs Facility ID:	F003033
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure 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
Scope:	Design and development, manufacture and distribution of in-vitro diagnostic test kits used in the diagnosis or detection of transmissible agents and sexually transmissible agents, cancer, prenatal screening, immune status, disease status, autoimmune status, drugs of abuse, cardiac markers, cardiovascular disease, endocrine disorders, fertility testing, pregnancy testing and the design and development, installation and service of in-vitro diagnostic analyzers.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1194196-690
Issue Date:	2025-10-23
Effective Date:	2025-11-02
Expiry Date:	2028-11-01

Certification officer: Dr. Matthias Fischer
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com or calling 1-888-743-4652.

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