Certificate

Certificate No.:	MD 3277299-150
Manufacturer:	**DRG International Inc.** 841 Mountain Avenue, 07081 NJ Springfield, USA
D-U-N-S No.:	07-515-0847
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, 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, protein metabolism, endocrine disorders, compatibility testing, 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.:	21238159 006
Issue Date:	2020-11-17
Effective Date:	2020-11-17
Expiry Date:	2022-11-01

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: MSc. I. Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.

TUV Rheinland of North America, Inc., 12 Commerce Road, Newtown, CT 06470, USA
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