Certificate

Certificate No.:	MD 3333620-70
Manufacturer:	**Dominion Biologicals Limited** 5 Isnor Drive Dartmouth, Nova Scotia B3B 1M1 Canada
D-U-N-S No.:	20-727-3194
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. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282
Scope:	Design and development, manufacture and distribution of IVD reagents including Monoclonal and Lectin Blood Grouping/ Typing Reagents for Direct and Indirect Hemagglutination, Blood Grouping/ Typing Control, Anti-Human Globulin Reagents, Potentiating Solution and Elution Kit.

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.:	3333620-70
Issue Date:	2020-12-21
Effective Date:	2020-12-21
Expiry Date:	2021-12-20

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M.Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000010119?locale=en or calling 1-888-743-4652.

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