# EC Design-Examination Certificate

TÜVRheinland®

**Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV (4)**

Registration No.: IL 1804155-1

Manufacturer: Dominion Biologicals Limited
5 Isnor Drive
Dartmouth, Nova Scotia B3B 1M1
Canada

Products: Blood Grouping Reagents

- NOVACLONE™ Diluent Control and Galileo
- NOVACLONE™ Anti-C II (RH2) Human Monoclonal IgM Rh Typing Reagent
- NOVACLONE™ Anti-E (RH3) Human Monoclonal IgM Rh Typing Reagent
- NOVACLONE™ Anti-e (RH5) Human Monoclonal IgM Rh Typing Reagent

Replaces Certificate, Registration No.: IL 60139701 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.