TÜVRheinland®

EC Design-Examination Certificate
Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60139701 0001

Report No.: 60239256 001

Manufacturer:

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

Product Identification:

Blood Grouping Reagents

(see attachment for products included)

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.

Expiry Date: 2022-04-10

Effective Date: 2019-05-29

Date: 2019-05-28

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60139701 0001
Report No.: 60239256 001

Manufacturer: Dominion Biologicals Limited
5 Isnor Drive
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Canada

Products:

- 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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-05-29

Dr. H. Lüdemann