TÜVRheinland®

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

Registration No.: IL 60139699 0001

Report No.: 60239254 001

Manufacturer:

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

Product Identification:

In vitro diagnostic reagent for determining ABO and RhD blood groups:

(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: 2024-02-01

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 60139699 0001
Report No.: 60239254 001

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

Products:

- NOVACLONE Anti-A Murine Monoclonal and Galileo
- NOVACLONE Anti-B Murine Monoclonal and Galileo
- NOVACLONE Anti-A,B Murine Monoclonal and Galileo
- NOVACLONE Anti-D IgM+IgG Monoclonal Blend and Galileo

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2019-05-29

Dr. H. Lüdemann