

EC Certificate

Directive 98/79/EC Annex IV, excluding Sections 4 and 6
Full Quality Assurance System
In Vitro Diagnostic Medical Devices

Registration No.: HL 60139708 0001

Report No.: 60239253 001

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

Products: see attachment for products included

Expiry Date: 2020-12-31

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Effective Date: 2019-05-29

Date: 2019-05-29

Notified Body


Dipl.-Ing. Sven Hoffmann



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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HL 60139708 0001
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Manufacturer: Dominion Biologicals Limited
5 Isnor Drive
Dartmouth, Nova Scotia B3B 1M1
Canada

Annex II List A 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
- 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
- NOVACLONE Anti-c (RH4) Human Monoclonal IgM Rh Typing Reagent

Date: 2019-05-29

Notified Body


Dipl.-Ing. Sven Hoffmann



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Manufacturer: Dominion Biologicals Limited
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Canada

Annex II List B Products:

- NOVACLONE Anti-IgG Murine Monoclonal Blend
- NOVACLONE Anti-IgG Murine Monoclonal Blend (Green)
- NOVACLONE Anti-IgG, -C3d Polyspecific Murine Monoclonal Blend
- NOVACLONE Anti-IgG, -C3d Polyspecific (Green) Murine Monoclonal Blend
- NOVACLONE Anti-C3d Murine Monoclonal

Date: 2019-05-29

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