TÜVRheinland®

# EC Design-Examination Certificate

## Directive 98/79/EC Annex IV, Section 4

## In Vitro Diagnostic Medical Devices

**Registration No.:** IL 60139698 0001

**Report No.:** 60239255 001

**Manufacturer:**

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

**Product Identification:**

In vitro diagnostic reagent for determining the Rh phenotype of atient or donor blood samples:

- NOVACLONE Anti-c (RH4) Human Monoclonal IgM Rh Typing Reagent

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.