

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1804155-1

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

Scope: Design and Development, Manufacture, Distribution of IVD reagents including Monoclonal and Lectin Blood Grouping/ Typing Reagents for Direct and Indirect Hemagglutination, Blood Grouping/Typing Control, Anti-Human Globulin Reagents, Potentiating Solution and Elution Kit.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

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