

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.

Report No.: 3333620-70
Effective date: 2022-01-01
Expiry date: 2023-12-31
Issue date: 2021-12-16



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