EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1804155-1
Manufacturer:	Dominion Biologicals Limited 5 Isnor Drive Dartmouth, Nova Scotia B3B 1M1 Canada
EUDAMED Single Registration No.:	CA-MF-000021925
Products:	Products of class C: HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0106: Other devices intended to be used for blood grouping W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY) Products of class D: HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0101: Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] W01030301 - ABO TYPING

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.
If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.
If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.:	1144168-20
Effective date:	2025-07-17
Expiry date:	2029-07-24
Issue date:	2025-07-17

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
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www.zlg.de
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EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1804155-1
Manufacturer:	Dominion Biologicals Limited 5 Isnor Drive Dartmouth, Nova Scotia B3B 1M1 Canada
EUDAMED Single Registration No.:	CA-MF-000021925
	IVR 0102: Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] W01030302 – Rhesus Typing
Authorized representative(s):	Immucor Medizinische Diagnostik GmbH Robert-Bosch-Strasse 3263303 Dreiech, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-07-25
1	Scope extension: Products of class D (W01030301)	2025-07-11
2	Scope extension: Products of class D (W01030302)	2025-07-17

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