

EU Certificate

Quality Management System REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices Annex IX Chapters I and 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)

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.: 1199107-20

Effective date: 2025-07-27

Expiry date: 2029-07-24

Issue date: 2026-07-27



Katja Mierisch
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 in vitro diagnostic medical devices with the identification number 0197.

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BS-IVDR-097



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Precisely Right.

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Quality Management System

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Annex IX Chapters I and III

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

EUDAMED Single
Registration No.: CA-MF-000021925

Products: 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

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

IVR 0106: Other devices intended to be used for blood grouping
W01030303 - ANTIBODY DETECTION
(IMMUNOHAEMATOLOGY)

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
3	Scope extension: Products of class D (W01030303)	2026-07-27



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