# 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

TÜVRheinland®

Registration No.: HX 1191616-1

Manufacturer:
**IMMUCOR**
**Medizinische Diagnostik GmbH**
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

EUDAMED Single Registration No.: DE-MF-000006494

Products: Products of class C:

HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY

IVR 0101: Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]
W0103030102 - ABO SERA

IVR 0106: Other devices intended to be used for blood grouping
W0103030102 - ABO SERA
W0103030501 - OTHER ANTIGEN TYPING REAGENTS
W0103030202 - RHESUS PHENOTYPES

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. 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. If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.10 is required before placing them on the market.

Report No.: 1129286-60

Effective date: 2023-11-10

Expiry date: 2026-10-25

Issue date: 2023-11-10

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-IVDR-097

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.

# 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**

TÜVRheinland®

Registration No.: HX 1191616-1

Manufacturer:

**IMMUCOR**
**Medizinische Diagnostik GmbH**
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

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)]
W0103030102 - ABO SERA

IVR 0102: Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
W0103030201 - RHESUS D
W0103030202 - RHESUS PHENOTYPES

IVR 0103: Devices intended to determine markers of the Kell system [Kel1 (K)]
W0103030501 - OTHER ANTIGEN TYPING REAGENTS

IVR 0106: Other devices intended to be used for blood grouping
W0103030499 - IMMUNOHAEMATOLOGY (BLOOD GROUPING) TESTS - OTHER

Authorised representative(s): N/A

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Registration No.: HX 1191616-1

Manufacturer:

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| Certificate history | | |
|---|---|---|
| Revision: | Description: | Issue date: |
| 0 | Initial certification | 2021-10-26 |
| 1 | Scope extension, added Products of class D - W0103030501 | 2023-05-26 |
| 2 | Scope extension, added Product of class D - W0103030499 | 2023-09-13 |
| 3 | Scope extension, added Products of class D - W0103030202 | 2023-09-28 |
| 4 | Scope extension, added Products of class D - W0103030201 | 2023-10-30 |
| 5 | Scope extension, added Products of class D - W0103030102 | 2023-11-10 |

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