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 1804147-1
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Products:	Products of class C HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 106: Other devices intended to be used for blood grouping W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY) W01030304 - IMMUNOHAEMATOLOGY CONTROLS W01030305 - OTHER ANTIGEN TYPING REAGENTS W01030399 - IMMUNOHAEMATOLOGY (BLOOD GROUPING) TESTS - OTHER

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.:	1141692-20
Effective date:	2025-06-25
Expiry date:	2028-05-10
Issue date:	2025-06-25

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 medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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IVR 201: Devices intended to be used for tissue typing (HLA A, B, DR) to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration
W01030399 - IMMUNOHAEMATOLOGY (BLOOD GROUPING) TESTS – OTHER

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)]
W01030304 - IMMUNOHAEMATOLOGY CONTROLS
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)]
W01030304 - IMMUNOHAEMATOLOGY CONTROLS
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)

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IVR 0103: Devices intended to determine markers of the Kell system [Kel1 (K)]
W01030304 - IMMUNOHAEMATOLOGY CONTROLS
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)

IVR 0104: Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)]
W01030304 - IMMUNOHAEMATOLOGY CONTROLS
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)

IVR 0105: Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)]
W01030304 - IMMUNOHAEMATOLOGY CONTROLS
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)
W01030305 - OTHER ANTIGEN TYPING

IVR 0106: Other devices intended to be used for blood grouping
W01030304 - IMMUNOHAEMATOLOGY CONTROLS
W01030303 - ANTIBODY DETECTION (IMMUNOHAEMATOLOGY)

Authorized representative(s):	Immucor Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 63303 Dreieich, Germany
Report No.:	1141692-20
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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-11
1	Scope extension, class D <<Weak D Cells>>	2023-09-19
2	Scope extension, class D <<corQC Test System, corQC EXTEND and Referencells>>	2023-11-21
3	Scope extension, class D <<Panocell, Panoscreen and Hemantigen>>	2025-04-16
4	Scope extension, class D <<Anti-Fya and Anti-Fyb (Monoclonal) (IgG) Gamma-clone>>	2025-05-06
5	Correction of Certificate history, class D <<Anti-Fy^{a} (Monoclonal) (IgG) Gamma-clone® and Anti-Fy^{b} (Monoclonal) Gamma-clone®>>	2025-06-25

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