EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1804147-9
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Classification:	Products of class D
General product group name:	HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0102 Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] IVR 0103 Devices intended to determine markers of the Kell system [Kel1 (K)] IVR 0104 Devices intended to determine markers of the Kidd system [JK1 (Jka), JK2 (Jkb)] IVR 0105 Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)] 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 II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	1204581-20
Effective date:	2026-04-21
Expiry date:	2030-08-11
Issue date:	2026-04-21

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 in vitro diagnostic medical devices with the identification number 0197.

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

TÜVRheinland®
Precisely Right.

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Registration No.:	IX 1804147-9
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Product name:	Capture-R® Ready-ID® Capture-R® Ready-ID® Extend I Capture-R® Ready-ID® Extend II
Models and types:	Capture-R Ready-ID (Ref: 0066204, 0066214) Capture-R Ready-ID Extend I (Ref: 0006454, 0006455) Capture-R Ready-ID Extend II (Ref: 0006456, 006457)
Basic UDI-DI:	08882340008KDV
Intended use:	Capture-R® Ready-ID® is intended for use in the qualitative identification of unexpected IgG antibodies to red blood cells by manual, semi-automated or automated solid phase red blood cell adherence methods for the purpose of blood transfusion to determine safety and compatibility with potential recipients. Capture-R® Ready-ID® Extend is intended for use as an adjunct to Capture-R® Ready-ID® in the qualitative identification of unexpected IgG antibodies to red blood cells. For laboratory professional use in testing blood specimens collected from patients and donors.
Authorized representative(s):	Immucor Medizinische Diagnostik GmbH Robert-Bosch-Strasse 32 63303 Dreieich Germany, DE-AR-000007083

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-08-12
1	Change of Basic UDI-DI	2026-04-21