

EU Certificate

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

Registration No.: IX 1804147-23

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.: 1191944-20

Effective date: 2026-05-04

Expiry date: 2031-05-03

Issue date: 2026-05-04



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.



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Product name: Capture-R® Positive Control Serum (Weak),
Capture-R® Negative Control Serum

Models and types: 0066236

Basic UDI-DI: 08882340007KDS

Intended use: Capture-R® Positive Control Serum (Weak) and Capture-R®
Negative Control Serum are for use as qualitative run controls
with Capture-R® Ready-Screen®, Capture-R® Ready-ID®
and Capture-R® Select by manual, semi-automated and
automated methods. For laboratory professional use.

Authorized representative(s): Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Straße 32, 63303 Dreieich
DE-AR-000007083

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-05-04



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