

EU Certificate

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

Registration No.: IX 1804147-10
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.: 1139306-20
Effective date: 2025-04-16
Expiry date: 2030-04-15
Issue date: 2025-04-16

This certificate can be validated on <https://www.certipedia.com>


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

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Precisely Right.

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Product name/
Models and types: Panocell-10 (REF 0003032)
Panocell-16 (REF 0002332)
Panocell-20 (REF 0005020)
Panocell-10, Ficin-Treated (REF 0002385)

Basic UDI-DI: 88823401W0103030303D001S9

Intended use: Panocell is intended for use in the qualitative identification of unexpected red blood cell blood group antibodies by manual hemagglutination for the purpose of blood transfusion to determine safety and compatibility with potential recipients. 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

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-04-16

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