EU Certificate

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

Registration No.:	IX 1804147-12
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.:	1141683-20
Effective date:	2025-04-16
Expiry date:	2030-04-15
Issue date:	2025-04-16

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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Registration No.:	IX 1804147-12
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Product name/ Models and types:	Panoscreen I and II (REF 0002380, 0002390), Panoscreen I, II and III (REF 0002381, 0002377), Panoscreen EXTEND (REF 0002383), Hemantigen (REF 0002223)
Basic UDI-DI:	88823401W0103030399D002Y2
Intended use:	Panoscreen is intended for use in the qualitative detection 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 use in automated semi-quantitative antibody titration on Galileo NEO and NEO Iris. For laboratory professional use in testing blood specimens collected from patients and donors. Hemantigen is intended for use in the qualitative detection 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.
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Registration No.:	IX 1804147-12
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EUDAMED Single Registration No.:	US-MF-000011568
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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