EU Certificate

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

Registration No.:	IX 1804147-19
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Classification:	Product of class D
General product group name:	HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0105: Devices intended to determine markers of the Duffy system [FY1 (Fya), FY2 (Fyb)] W01030305 - Other antigen typing
Product name:	Anti-Fy^{b} (Monoclonal) Gamma-clone®
Models and types:	0004818
Basic UDI-DI:	88823401W0103030501D003SR

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.:	1141692-20
Effective date:	2025-06-25
Expiry date:	2030-06-04
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
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BS-MDR-091

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Intended use:	Anti-Fy^{b} (Monoclonal) Gamma-clone® blood grouping reagent is intended for the qualitative detection of the Fy^{b} (FY2) antigen on red blood cells by direct agglutination test for the purpose of blood transfusion to determine the safety and compatibility with potential recipients. For laboratory professional use in testing of blood specimens collected from patients and donors by manual tube and automated microplate tests.
Authorized representative(s):	Immucor Medizinische Diagnostik GmbH Robert-Bosch-Str. 32, 63303 Dreieich Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-06-05
1	Correction of Product name	2025-06-25

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