

# EU Certificate

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

Registration No.: IX 1804147-18

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 0105: Devices intended to determine markers of the Duffy  
system [FY1 (Fya), FY2 (Fyb)]

W01030305 - OTHER ANTIGEN TYPING

Product name: Anti-Fya (Monoclonal) (IgG) Gamma-clone  
Models and types: 0066430

Basic UDI-DI: 088823400010M2L

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: 2030-06-04

Issue date: 2026-04-21



Dr. Volker Schlueter  
TÜV Rheinland LGA Products GmbH  
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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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Intended use: Anti-Fya (Monoclonal) (IgG) Gamma-clone® blood grouping reagent is intended for the qualitative detection of the Fya (FY1) antigen on red blood cells by indirect 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-Strasse 32  
63303 Dreieich Germany, DE-AR-000007083

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-06-05
1	Change of Basic UDI-DI	2026-04-21



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