EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX

TÜVRheinland®

Registration No.:	IX 1804147-1
Manufacturer:	**Immucor, Inc.** 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
General product group name:	Products of class D HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY 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 W01030304 - IMMUNOHAEMATOLOGY CONTROLS
Product name: Models and types:	Monoclonal Control 0066089 (10x10 ml) 0066087 (1x10 ml)
Basic UDI-DI:	88823401W0103030499D000YF

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.:	1118974-20
Effective date:	2023-05-11
Expiry date:	2028-05-10
Issue date:	2023-05-11

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Benannt durch/Designated by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
BS-IVDR-097

Katja Mierisch
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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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3130 Gateway Drive
Norcross GA 30071
USA

Intended use: Monoclonal Control is intended for use as a control reagent to detect false-positive reactions (e.g.,due to sensitized red blood cells (direct antiglobulin test positive), potent autoagglutinins or abnormal serum proteins) when tested alongside Immucor monoclonal blood grouping reagents listed in the materials section. For laboratory professional use with qualitative manual slide, tube and automated microplate tests using blood specimens collected from patients and donors.

Authorised representative(s):
Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-11

Report No.: 1118974-20

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