

EU Certificate

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

Registration No.: IX 1804147-17

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 0104 Devices intended to determine markers of the Kidd
system [JK1 (Jka), JK2 (Jkb)]

W01030305 - OTHER ANTIGEN TYPING

Product name: Anti-Jkb (Monoclonal) Gamma-clone®
Models and types: 0066427

Basic UDI-DI: 88823401W0103030501D001SM

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.: 1141690-20

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Expiry date: 2030-10-21

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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 medical devices with the identification number 0197.



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