

EU Certificate

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



Registration No.: IX 1804147-4

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 0101: Devices intended to determine markers of the ABO system [A (ABO1),
B (ABO2), AB (ABO3)]
W01030301 - ABO TYPING

Product name: Referencells -4 (Group A1, A2, B and O), REF: 0002338
Models and types: Referencells -2 (Group A1 and B), REF: 0002345
Referencells -1 (Group A2), REF: 0002342

Basic UDI-DI: 88823401W0103030101D000QF

Intended use: Referencells® (Pooled Cells) is intended for detection of ABO isohemagglutinins
by qualitative hemagglutination tube and microplate tests by manual and
automated methods 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.

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.: 1132938-20

Effective date: 2023-11-20

Expiry date: 2028-11-19

Issue date: 2023-11-20



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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Authorised representative(s): Immucor Medizinische Diagnostik GmbH
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Certificate history		
Revision	Description:	Issue Date:
0	Initial certification	2023-11-20

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