# EU Certificate

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

TÜVRheinland®

| | |
|---|---|
| Registration No.: | IX 1804147-5 |
| Manufacturer: | **Immucor, Inc.**<br>3130 Gateway Drive<br>Norcross GA 30071<br>USA |
| EUDAMED Single Registration No.: | US-MF-000011568 |
| General product group name: | Products of class D<br><br>HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY<br><br>IVR 0102: Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]<br>Haematology / haemostasis / immunohaematology / histology / cytology<br>W01030304 - IMMUNOHAEMATOLOGY CONTROLS |
| Product name: | Weak D Cells |
| Models and types: | 0002995 |
| Basic UDI-DI: | 88823401W0103030499D001YH |
| Intended use: | Weak D Cells is intended for use in quality control testing of qualitative weak D tests using Anti-D Blood Grouping Reagents by manual tube test.<br>For professional laboratory use. Weak D Cells is not used to test diagnostic specimens. |

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.: | 1132944-20 |
| Effective date: | 2023-09-19 |
| Expiry date: | 2028-09-18 |
| Issue date: | 2023-09-19 |

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

1132944-20
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.

# EU Certificate

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

TÜVRheinland®

Registration No.: IX 1804147-5

Manufacturer:

**Immucor, Inc.**
3130 Gateway Drive
Norcross GA 30071
USA

Authorised representative(s):

Immucor Medizinische Diagnostik GmbH
Robert-Bosche-Strasse 32
63303 Dreieich Germany

| Certificate history | | |
|---|---|---|
| Revision | Description: | Issue Date: |
| 0 | Initial certification | 2023-09-19 |
| | | |
| | | |

Report No.: 1132944-20

Effective date: 2023-09-19

Expiry date: 2028-09-18

Issue date: 2023-09-19

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

1132944-20
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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.