

EU Certificate

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



Registration No.: IX 1804147-5

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 0102: Devices intended to determine markers of the Rhesus system [RH1
(D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
Haematology / haemostasis / immuno-haematology / histology / cytology
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.
For professional laboratory use. Weak D Cells is not used to test diagnostic
specimens.

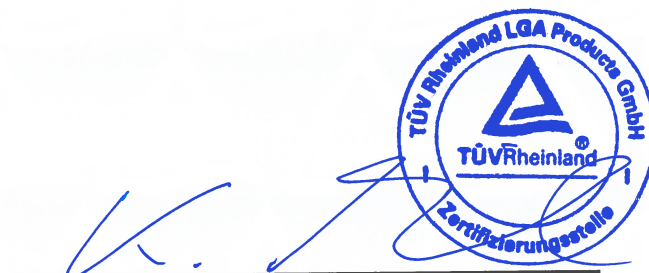
The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the
REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has
established and maintains a technical documentation defined by Annex IX, Chapter II, Section 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



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.

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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 |
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Benannt durch/Designated by
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