

EU Certificate

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

Registration No.: IX 1804147-5
Manufacturer: Immucor, Inc.
3130 Gateway Drive
Norcross GA 30071
USA

EUDAMED Single
Registration No.: US-MF-000011568

Classification: Products of class D

General product group name: 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)]

W01030304 - IMMUNOHAEMATOLOGY CONTROLS

Product name: Weak D Cells
Models and types: REF: 0002995

Basic UDI-DI: 08882340005LDN

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.: 1204581-20
Effective date: 2026-04-21
Expiry date: 2028-09-18
Issue date: 2026-04-21



Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
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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 in vitro diagnostic medical devices with the identification number 0197.



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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Precisely Right.

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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.

Authorized representative(s): Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich Germany, DE-AR-000007083

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-09-19
1	Change of Basic UDI-DI	2026-04-21

