EU Certificate

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

Registration No.:	IX 1804147-6
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 0106: Other devices intended to be used for blood grouping W01030304 - IMMUNOHAEMATOLOGY CONTROLS
Product name: Models and types:	Checkcell, Checkcell (Weak) Checkcell, REF 0002224, 0002225 Checkcell (Weak), REF 0002226, 0002227.
Basic UDI-DI:	08882340006LDR

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:	2030-08-19
Issue date:	2026-04-21

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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
www.zlg.de
BS-IVDR-097

TÜVRheinland®
Precisely Right.

EU Certificate

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

Registration No.:	IX 1804147-6
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Intended use:	Checkcell® and Checkcell® (Weak) are intended for quality control of Anti-Human Globulin for the qualitative detection of active anti-IgG to confirm the validity of negative antiglobulin tests by manual methods. For laboratory professional use. Checkcell® and Checkcell® (Weak) are not used directly 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	2025-08-20
1	Change of Basic UDI-DI	2026-04-21