EU Certificate

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

Registration No.:	IX 1804147-2
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 102: Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]
IVR 103: Devices intended to be used for blood grouping with regard to Kell system [Kel1 (K)]

W01030304 - IMMUNOHAEMATOLOGY CONTROLS

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:	2028-11-19
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

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Registration No.:	IX 1804147-2
Manufacturer:	Immucor, Inc. 3130 Gateway Drive Norcross GA 30071 USA
EUDAMED Single Registration No.:	US-MF-000011568
Product name: Models and types:	corQC EXTEND Complete, REF: 0066297 corQC EXTEND Standard, REF: 0066296 corQC EXTEND 1, 2 and 3, REF: 0002417
Basic UDI-DI:	08882340003LDG
Intended use:	corQC® EXTEND is intended for use in qualitative quality control testing of RH and K blood grouping reagents. For use in manual tube test and automated use on Galileo NEO and NEO Iris. For professional laboratory use. corQC® EXTEND 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	2023-11-20
1	Change of Basic UDI-DI	2026-04-21

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