EU Certificate

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

Registration No.:	IX 1804147-7
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 0101: Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)] IVR 0102: Devices intended to be used for blood grouping with regard to Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] W01030304 - IMMUNOHAEMATOLOGY CONTROLS
Product name:	corQC Test System
Models and types:	0002410
Basic UDI-DI:	08882340004LDK

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:	2028-11-14
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 www.zlg.de
BS-IVDR-097

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Precisely Right.

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Intended use:	corQC® Test System is intended for qualitative quality control testing for routine ABO, RH, Anti-Human Globulin, potentiator and antibody detection blood bank reagents. For use in manual tube tests. For professional laboratory use. corQC® Test System 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	2023-11-15
1	Change of Basic UDI-DI	2026-04-21