EU Certificate

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

TÜVRheinland®

Registration No.: IX 1804147-7

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 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: 88823401W0103030402D000SD

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.: 1137731-20

Effective date: 2023-11-15

Expiry date: 2028-11-14

Issue date: 2023-11-15

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

Katja Mierisch
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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.

EU Certificate

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

TÜVRheinland®

Registration No.: IX 1804147-5

Manufacturer: **Immucor, Inc.**
3130 Gateway Drive
Norcross GA 30071
USA

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.

Authorised representative(s): Immucor Medizinische Diagnostik GmbH
Robert-Bosche-Strasse 32
63303 Dreieich Germany

Certificate history		
Revision	Description:	Issue Date:
0	Initial certification	2023-11-15

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