

EU Certificate

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

Registration No.: IX 1804147-3
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 determine markers of the
Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c),
RH5 (e)]
IVR 0103: Devices intended to determine markers of the Kell
system [Kel1 (K)]
IVR 0106: Other devices intended to be used for blood
grouping
W01030304 – IMMUNOHAEMATOLOGY CONTROLS

Product name: WB corQC

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.: 1132936-20
Effective date: 2026-05-04
Expiry date: 2031-05-03
Issue date: 2026-05-04



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.

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Models and types: REF: 0066090

Basic UDI-DI: 08882340007LDU

Intended use: WB corQC is intended for qualitative quality control testing of ABO, RH, K, and antibody detection blood bank reagents. For automated use on Galileo Echo and Echo Lumena. For professional laboratory use. WB corQC is not used to test diagnostic specimens.

Authorized representative(s): Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Str. 32, 63303 Dreieich
Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2026-05-04

