EU Certificate

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

TÜVRheinland®

Registration No.:	IX 1191616-1
Manufacturer:	**IMMUCOR** **Medizinische Diagnostik GmbH** Robert-Bosch-Str. 32 63303 Dreieich Germany
EUDAMED Single Registration No.:	DE-MF-000006494
General product group name:	Products class D HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0103 Devices intended to determine markers of the Kell system [Kel1 (K)] W0103030501 - OTHER ANTIGEN TYPING REAGENTS
Product name: Models and types:	Anti-K (Kell) quick 0008050, 0008015
Basic UDI-DI:	88823405W0103030501D15KE
Intended use:	Anti-K (Kell) quick, Coombs-reactive, human IgG is an in vitro diagnostic Blood Group Reagent used to detect the K (Kell) erythrocyte antigen of donors and recipients by indirect hemagglutination test for the purpose of a blood transfusion to determine the safety and compatibility with recipients. Anti-K (Kell) quick, Coombs-reactive, human IgG is intended for Manual Tube Test (qualitative).
Authorised representative(s):	N/A

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.:	1120609-20
Effective date:	2023-11-22
Expiry date:	2028-11-21
Issue date:	2023-11-22

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

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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.

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-11-22

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