EU Certificate

Technical Documentation Assessment

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

TÜVRheinland®

Registration No.:	IX 1191616-11
Manufacturer:	**IMMUCOR** **Medizinische Diagnostik GmbH** Robert-Bosch-Strasse 32 63303 Dreieich Germany
EUDAMED Single Registration No.:	DE-MF-000006494
General product group name:	Products of 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:	immuClone (2) Anti-K IgM
Models and types:	immuClone (2) Anti-K IgM and immuClone (2) Anti-K Automated IgM
Basic UDI-DI:	88823405W0103030501D31KC

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.:	1122112-20
Effective date:	2023-05-25
Expiry date:	2028-05-24
Issue date:	2023-05-25

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

Dr. H. Lüdemann
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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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Manufacturer:

IMMUCOR
Medizinische Diagnostik GmbH
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

Intended use:

immuClone® (2) Anti-K IgM and immuClone® (2) Anti-K Automated IgM are Blood Group Reagents used to detect the K (Kell) erythrocyte antigen from donors and recipients by direct hemagglutination test for the purpose of a blood transfusion to ensure the safety and compatibility between the patient and the blood component selected for transfusion. For Manual Tube, Slide, Microplate and Automated

Microplate Tests (qualitative). immuClone® (2) Anti-K IgM is intended for manual Tube, Slide and Microplate Tests (qualitative). immuClone® (2) Anti-K Automated IgM is intended for Automated Microplate Tests (qualitative).

Authorised representative(s): **N/A**

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-25

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