EU Certificate

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

TÜVRheinland®

Registration No.: IX 1191616-12

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: immuClone (1) Anti-K IgM, REF: 0008016, 0008026
Models and types: immuClone (1) Anti-K Galileo IgM, REF: 0066020

Basic UDI-DI: 88823405W0103030501D26KK

Intended use: immuClone® (1) Anti-K IgM and immuClone® (1) Anti-K Galileo IgM are in vitro diagnostic 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® (1) Anti-K IgM is intended for Manual Tube, Slide and Microplate Tests (qualitative). immuClone® (1) Anti-K Galileo IgM is intended for Automated Microplate Tests (qualitative).

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.: 1123405-20

Effective date: 2023-11-22

Expiry date: 2028-11-21

Issue date: 2023-11-22

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

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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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Authorised representative(s): N/A

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

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