EU Certificate

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

TÜVRheinland®

Registration No.:	IX 1191616-6
Manufacturer:	**IMMUCOR** **Medizinische Diagnostik GmbH** Robert-Bosch-Strasse 32 63303 Dreieich Germany
EUDAMED Single Registration No.:	DE-MF-000006494
General product group name:	Products class D HAEMATOLOGY / HAEMOSTASIS / IMMUNOHAEMATOLOGY / HISTOLOGY / CYTOLOGY IVR 0102: Devices intended to determine markers of the Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)] W0103030202 - RHESUS PHENOTYPES
Product name: Models and types:	immuClone (2) Anti-c IgM - REF: 0007307, 0007305, 0007317, 0007315 immuClone (2) Anti-c Galileo IgM - REF: 0066014
Basic UDI-DI:	88823405W0103030202D28JP

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.:	1120780-20
Effective date:	2024-04-18
Expiry date:	2028-09-27
Issue date:	2024-04-18

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
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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
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63303 Dreieich
Germany

Intended use: immuClone® (2) Anti-c IgM and immuClone® (2) Anti-c Galileo IgM are in vitro diagnostic Blood Group Reagents used to detect the c 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-c IgM is intended for Manual Tube, Slide and Microplate Tests (qualitative). immuClone® (2) Anti-c Galileo IgM is intended for Automated Microplate Tests (qualitative).

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

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-09-28
1	Correction of certificate number on page 2	2024-04-18

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