EU Certificate

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

TÜVRheinland®

Registration No.: IX 1191616-8

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 102: 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: immuClone (2) Anti-E IgM - REF: 0007407, 0007405, 0007417, 0007415
Models and types: immuClone (2) Anti-E Galileo IgM - REF: 0066016

Basic UDI-DI: 88823405W0103030202D29JR

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.: 1120779-20

Effective date: 2023-11-29

Expiry date: 2028-11-28

Issue date: 2023-11-29

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.

EU Certificate

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

TÜVRheinland®

Registration No.: IX 1191616-8

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

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

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

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-11-29

Report No.: 1120779-20

Effective date: 2023-11-29

Expiry date: 2028-11-28

Issue date: 2023-11-29

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

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.