

# EU Certificate

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



Registration No.: IX 1191616-15

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)]  
W0103030201 - RHESUS D

Product name: immuClone Anti-D rapid IgM, REF: 0007117, 0007127  
Models and types: immuClone Anti-D rapid Galileo IgM, REF: 0066008, 0066085

Basic UDI-DI: 88823405W0103030201D38

Intended use: immuClone Anti-D rapid IgM and immuClone Anti-D rapid Galileo IgM are in vitro diagnostic Blood Grouping Reagents used to detect the Rhesus D (Rh D) 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).

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.

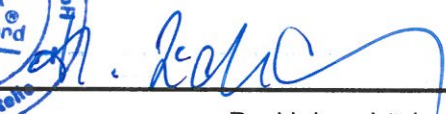
Report No.: 1123412-20

Effective date: 2023-12-06

Expiry date: 2028-12-05

Issue date: 2023-12-06



  
Dr. Heiner 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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immuClone Anti-D rapid IgM is intended for Manual Tube, Slide, and Microplate Tests (qualitative). immuClone Anti-D rapid Galileo IgM is intended for Automated Microplate Tests (qualitative).

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

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-12-06


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