EU Certificate

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

TÜVRheinland®

Registration No.: IX 1191616-19

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 0101: Devices intended to determine markers of the ABO system [A (ABO1), B (ABO2), AB (ABO3)]
W0103030102 - ABO SERA

Product name: Models and types: immuClone Anti-A IgM, REF: 0066001, 0066080

Basic UDI-DI: 88823405W0103030102D32HZ

Intended use: immuClone® Anti-A IgM is an in vitro diagnostic Blood Grouping Reagent used to detect the A 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.: 1129286-20

Effective date: 2023-11-10

Expiry date: 2028-11-09

Issue date: 2023-11-10

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
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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	2023-11-10

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