

# EC Certificate

**Full Quality Assurance System**  
**Directive 98/79/EC on In Vitro Diagnostic Medical Devices,**  
**Annex IV excluding (4, 6)**

Registration No.: HL 1191616-1

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

Products: Annex II List A Products:

- immuClone Anti-A IgM
- immuClone Anti-B IgM
- immuClone Anti-A,B IgM
- immuClone Anti-D rapid IgM and Galileo
- immuClone Anti-D duo IgM + IgG and Galileo
- immuClone Anti-CDE IgM + IgG and Galileo
- immuClone (1) Anti-C IgM and Galileo
- immuClone (1) Anti-c IgM and Galileo
- immuClone (1) Anti-E IgM and Galileo
- immuClone (1) Anti-e IgM and Galileo
- immuClone (2) Anti-C IgM and Galileo
- immuClone (2) Anti-c IgM and Galileo
- immuClone (2) Anti-E IgM and Galileo
- immuClone (2) Anti-e IgM and Galileo
- immuClone Rh-Hr Control and Galileo

The Notified Body hereby declares that the requirements of Annex IV, excluding section 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 3347722-570

Effective date: 2021-04-14

Expiry date: 2024-05-26

Issue date: 2021-04-14



Dipl.-Ing. Sven Hoffmann  
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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

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Robert-Bosch-Strasse 32  
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Germany

**Annex II List A Products:**

- immuClone (1) Anti-K (Kell) IgM and Galileo
- immuClone (2) Anti-K (Kell) IgM
- Automated immuClone Anti-K (Kell) Galileo IgM
- immuClone Anti-D fast IgM
- Anti-K (Kell) quick

**Annex II List B Products:**

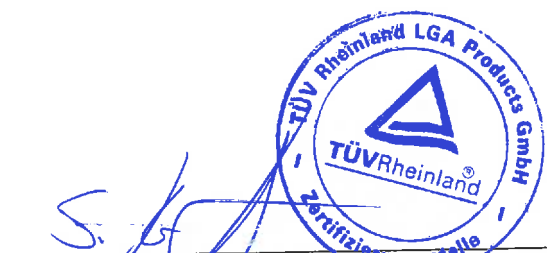
- immuClone Anti-Jk(a) IgM
- immuClone Anti-Jk(b) IgM
- Anti-Fy(a)
- Anti-Fy(b)
- Anti-Human Globulin Serum (Anti-IgG, -C3d) green
- Anti-Jk(a) micro
- Anti-Jk(b) micro
- Anti-Fy(a) micro
- Anti-Fy(b) micro
- Negative Control micro

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