

**EC Design-Examination Certificate**  
**Directive 98/79/EC Annex IV, Section 4**  
**In Vitro Diagnostic Medical Devices**

**Registration No.:** IL 60139594 0001

**Report No.:** 60239190 001

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

**Product**

**Identification:** In vitro diagnostic reagents, including control material,  
for determining blood groups: rhesus (C, c, D, E, e)  
  
(see attachments for products included)

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.


**Expiry Date:** 2023-12-07

**Effective Date:** 2019-05-29

**Date:** 2019-05-28



**Notified Body**

  
Dr. H. Lüdemann

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** IL 60139594 0001  
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**Products:**

- immuClone Anti-D rapid IgM and Galileo
- immuClone Anti-D fast IgM
- 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

**Date:** 2019-05-29



**Notified Body**

  
**Dr. H. Lüdemann**