TÜVRheinland®

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

Registration No.: IL 60139592 0001

Report No.: 60239191 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: Kell (K)

(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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60139592 0001
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Products:

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

Date: 2019-05-29

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Dr. H. Lüdemann