EC Certificate

TÜVRheinland®

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

TÜV Rheinland LGA Products GmbH · TÜVRheinland · Zertifizierstelle

Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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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

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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Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

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Date August 12, 2022

Restriction of certificate registration no.: IL 60139592 0001 and HL 1191616-1
EC Design-examination file: IMD_03.TF.0001-Technical File (IVDD List A)
Product: Automated immuClone Anti-K (Kell) Galileo IgM

Dear Ms. Wilhelmi,

based on the information you provided to TÜV Rheinland LGA Products GmbH on 26th July 2022 (verbally) and 27th July 2022 / 1st August 2022 (in writing) we conclude that the above mentioned EC Design-examination file does provide incorrect information about the above mentioned product.

The incorrect information is associated with the monoclonal clone used in the product and subsequently also with additional information in the EC Design-examination file (e.g. information in the Instruction for Use).

Therefore, the EC Design-examination certificate according to Directive 98/79/EC, Annex IV, section 4 *Galileo IgM* and the full quality Assurance System EC certificate, Annex IV excluding (4, 6) are restricted and the product *Automated immuClone Anti-K (Kell) is* no longer covered by the certified conformity assessment procedures with immediate effect.

With immediate effect the above mentioned product must no longer be marketed with the identification marking of the Notified Body 0197.

Beyond that we are obliged to inform the German Institute for Medical Documentation and Information (DMIDS) about the restriction of both certificates according to German legislation.

Best regards,

X

Signiert von: Katja Mierisch

Katja Mierisch

Certification body

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