

## Declaration of Conformity

European Community Council Directive 98/79/EC

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

IMMUCOR Medizinische Diagnostik GmbH, hereby declares that the device(s) listed in Appendix A meet the provisions of directive 98/79/EC on in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer. The List A and List B devices are in accordance with Annex IV (Full Quality Assurance) of directive 98/79/EC. The Self-Declared Devices are in accordance with Annex III (EC Declaration of Conformity) of directive 98/79/EC.

Standards and Directives used in support of conformance to directive 98/79/EC on in vitro diagnostic medical devices:

|                     |  |
|---------------------|--|
| EN ISO 13485:2016   | Medical Devices – Quality Management Systems - Requirements for regulatory purposes.   |
| EN ISO 14971:2012   | Medical Devices-Application of risk management to medical devices.   |
| EN 13612:2002       | Performance evaluation of in vitro diagnostic medical devices  |
| EN 23640:2015       | In-vitro Diagnostic Medical Devices – Evaluation of stability testing of in vitro diagnostic reagents                                  |
| EN ISO 18113-1:2011 | In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements |
| EN ISO 18113-2:2011 | Information supplied by the manufacturer (labelling) with in vitro diagnostic reagents for professional use                            |
| ISO 15223-1:2016    | Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied                              |
| EN 13641:2002       | Elimination or reduction of risk of infection related to in vitro diagnostic reagents  |
| EN 62366:2008       | Medical devices - Application of usability engineering to medical devices  |

This declaration is issued under the sole responsibility of Immucor Medizinische Diagnostik GmbH by

Place, date of issue: Dreieich, 29MAY2019



**Maria Wilhelmi**  
Director RA/QA Europe  
IMMUCOR Medizinische Diagnostik GmbH

**Annex II List A and B devices in accordance with Annex IV of the directive 98/79/EC.**

**Classification: List A, Annex II**

| <b>Products</b>                         | <b>Product Number(s)</b>           |
|---|------------------------------------|
| immuClone Anti-A IgM                    | 0066001; 0066080;                  |
| immuClone Anti-B IgM                    | 0066002; 0066081;                  |
| immuClone Anti-A,B IgM                  | 0066003; 0066082;                  |
| immuClone Anti-D rapid IgM              | 0007117; 0007127                   |
| immuClone Anti-D rapid Galileo IgM      | 0066008; 0066085                   |
| immuClone Anti-D fast IgM               | 0007116; 0007126                   |
| immuClone Anti-D duo IgM + IgG          | 0006196; 0006199                   |
| immuClone Anti-D duo Galileo IgM + IgG  | 0066009; 0066086                   |
| immuClone Anti-CDE IgM + IgG            | 0006820; 0006821                   |
| immuClone Anti-CDE Galileo IgM + IgG    | 0066010                            |
| immuClone (1) Anti-C IgM                | 0007206; 0007204; 0007216; 0007214 |
| immuClone (1) Anti-C Galileo IgM        | 0066011                            |
| immuClone (1) Anti-c IgM                | 0007306; 0007304; 0007316; 0007314 |
| immuClone (1) Anti-c Galileo IgM        | 0066013                            |
| immuClone (1) Anti-E IgM                | 0007406; 0007404; 0007416; 0007414 |
| immuClone (1) Anti-E Galileo IgM        | 0066015                            |
| immuClone (1) Anti-e IgM                | 0007506; 0007504; 0007516; 0007514 |
| immuClone (1) Anti-e Galileo IgM        | 0066017                            |
| immuClone (2) Anti-C IgM                | 0007207; 0007205; 0007217; 0007215 |
| immuClone (2) Anti-C Galileo IgM        | 0066012                            |
| immuClone (2) Anti-c IgM                | 0007307; 0007305; 0007317; 0007315 |
| immuClone (2) Anti-c Galileo IgM        | 0066014                            |
| immuClone (2) Anti-E IgM                | 0007407; 0007405; 0007417; 0007415 |
| immuClone (2) Anti-E Galileo IgM        | 0066016                            |
| immuClone (2) Anti-e IgM                | 0007507; 0007505; 0007517; 0007515 |
| immuClone (2) Anti-e Galileo IgM        | 0066018                            |
| immuClone (1) Anti-K (Kell) IgM         | 0008016; 0008026                   |
| immuClone (1) Anti-K (Kell) Galileo IgM | 0066020                            |
| immuClone (2) Anti-K (Kell) IgM         | 0008014                            |
| immuClone (2) Anti-K (Kell) Galileo IgM | 0066038                            |
| Anti-K (Kell) quick                     | 0008015; 0008050                   |

**Classification: List A, Annex II - continued**

| Products                                      | Product Number(s) |
|---|-------------------|
| Automated immuClone Anti-K (Kell) Galileo IgM | 0066088           |
| immuClone Rh-Hr Control                       | 0006720; 0006721  |
| immuClone Rh-Hr Control Galileo               | 0066006; 0066083  |

**Classification: List B, Annex II**

| Products   | Product Number(s)         |
|--|---------------------------|
| immuClone Anti-Jk(a)                               | 0008306                   |
| immuClone Anti-Jk(b)                               | 0008315                   |
| Anti-Fy(a)   | 0008205                   |
| Anti-Fy(b)   | 0008210                   |
| Anti-Jk(a) micro                                   | 0066302                   |
| Anti-Jk(b) micro                                   | 0066303                   |
| Anti-Fy(a) micro                                   | 0066300                   |
| Anti-Fy(b) micro                                   | 0066301                   |
| Negative Control micro                             | 0066299                   |
| Anti-Human Globulin Serum, (Anti-IgG, -C3d), green | 0004810; 0004848; 0004850 |

Conformity assessment according Annex IV is performed by:

**TÜV Rheinland LGA Products GmbH**

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Notified Body number: 0197

**Self-Declare devices in accordance with Annex III of directive 98/79/EC (EC Declaration of Conformity)**

**Classification: Self Certify (Self-Declare), Annex III**

| Products                                  | Product Number(s) |
|---|-------------------|
| immuClone Anti-M                          | 0009506           |
| immuClone Anti-M Galileo                  | 0066021           |
| immuClone Anti-N IgM                      | 0009605           |
| immuClone Anti-S IgM                      | 0009905           |
| immuClone Anti-s IgM                      | 0009959           |
| immuClone Anti-H IgM                      | 0009525           |
| immuClone Anti-H Galileo IgM              | 0066005           |
| immuClone Anti-Le(a) IgM                  | 0004162           |
| immuClone Anti-Le(b) IgM                  | 0004164           |
| immuClone Anti-C <sup>w</sup> IgM         | 0007603           |
| immuClone Anti-C <sup>w</sup> Galileo IgM | 0066019           |
| immuClone Anti-P(1) IgM                   | 0008150           |
| Anti-C <sup>w</sup> High Protein          | 0006605           |
| Anti-Lu(a)                                | 0008108           |
| Anti-Lu(b)                                | 0008109           |
| Anti-IgM                                  | 0003003           |
| Anti-IgA                                  | 0003002           |
| Anti-Co(a)                                | 0099100           |
| Anti-Co(b)                                | 0008307           |
| Anti-Wr(a)                                | 0099120           |
| Anti-k (Cellano) (2)                      | 0008055           |
| Anti-Lu(a) (2)                            | 0008110           |
| Anti-Lu(b) (2)                            | 0008111           |
| Anti-Kp(a) (2)                            | 0008208           |
| Anti-Kp(b) (2)                            | 0008209           |
| Anti-Js(b)                                | 0099140           |
| Anti-S micro                              | 0066304           |
| Anti-s micro                              | 0066305           |
| Anti-k micro                              | 0066306           |
| Anti-C <sup>w</sup> micro                 | 0066307           |
| Anti-A hel                                | 0005602           |
| Anti-A(1) (Lectin)                        | 0005405           |
| Anti-A(1) (Lectin) Galileo                | 0066004           |
| Anti-H (Lectin)                           | 0005505           |
| Galileo System Liquid Concentrate         | 0066056           |



| <b>Products</b>         | <b>Product Number(s)</b> |
|-------------------------|--------------------------|
| Galileo Diluent         | 0066055; 0066058         |
| Kleihauer Kit           | 0098100                  |
| Bromelin                | 0004110; 0004120         |
| AB Serum, antibody free | 0099301                  |
| Coombs Control Serum    | 0099430                  |
| immucor TP-12           | 0032001                  |