IMMUCOR

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

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

Classification: List A, Annex II

Products	Product Number(s)
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

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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
Tillystraße 2
90431 Nürnberg
Country: Germany

Phone: +49 (0) 9116555225
Fax: +49 (0) 9116555226

Notified Body number: 0197

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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^w IgM	0007603
immuClone Anti-C^w Galileo IgM	0066019
immuClone Anti-P(1) IgM	0008150
Anti-C^w 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^w 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

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