

DECLARATION OF CONFORMITY



Manufacturer:

CE-IMMUNDIAGNOSTIKA GmbH
Karl-Landsteiner-Straße 6, D-69151 Neckargemünd
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Revision: **30/01-2020**

Valid until: **30/06-2021**

As exclusively responsible manufacturer we herewith declare that the below mentioned products meet the provisions of the Council Directive Annex I 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer.

Supervising authority :

Regierungspräsidium Karlsruhe

Notified Body:

Identification Number: 0483

mdc medical device certification GmbH
Kriegerstraße 6
70191 Stuttgart
Germany

Conformity Assessment:

For devices listed in List A and B of Annex II, the manufacturer has applied the procedure for the EC Declaration of Conformity in accordance with Annex IV (Full Quality Assurance), for all other devices the procedure according to Annex III of Directive 98/79/EC has been applied.

Place, Date of Issue:

Neckargemünd, 30/01-2020

Signature of QMB:

(Vanessa Ritter)

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Products: List A/List B

REF / Catalogue No.	Product designation	Clone	Classification
A-mono-11H5-10	Anti-A A-11H5	A-11H5	List A
A-mono-BIRMA-10	Anti-A Birma-1	BIRMA-1	List A
B-mono-6F9-10	Anti-B B-6F9	B-6F9	List A
B-mono-LB2-10	Anti-B LB-2	LB-2	List A
AB-mono5E10-10	Anti-AB A-5E10-B-2D7	A-5E10+B-2D7	List A
C-mono-MS24-05 C-mono-MS24-10	Anti-C MS24	MS-24	List A
C-mono-MS273-05 C-mono-MS273-10	Anti-C MS273	MS-273	List A
c-mono-MS33-05 c-mono-MS33-10	Anti-c MS33	MS-33	List A
c-mono-MS35-05 c-mono-MS35-10	Anti-c MS35	MS-35	List A
D-mono-MS201-10	Anti-D MS-201	MS-201	List A
D-mono-RUM-10	Anti-D RUM-1	RUM-1	List A
D-mono-blend-TH-10	Anti-D blend TH-28/MS-26	TH-28/MS-26	List A
D-mono-blend-175-10	Anti-D blend 175 2-415 1E4	D175-2;D415 1E4	List A
D-inco-10	Anti-D incomplete	-	List A
E-mono-MS12-05 E-mono-MS12-10	Anti-E MS12/MS260	MS-12/MS-260	List A
E-mono-MS80-05 E-mono-MS80-10	Anti-E MS80/MS258	MS-80/MS-258	List A
e-mono-MS16-05 e-mono-MS16-10	Anti-e MS16/MS21/MS63	MS-16/MS-21/MS-63	List A
e-mono-MS62-05 e-mono-MS62-10	Anti-e MS62/MS69	MS-62/MS-69	List A
Kell-mono-MS56-05 Kell-mono-MS56-10	Anti-Kell MS56	MS-56	List A
Kell-mono-AEK4-05 Kell-mono-AEK4-10	Anti-Kell AEK4	AEK4	List A
Kell-coom-05 Kell-coom-10	Anti-Kell coombsreactive	-	List A
Fya-coom-02 Fya-coom-05	Anti-Fy ^a coombsreactive	-	List B
Fyb-coom-02 Fyb-coom-05	Anti-Fy ^b coombsreactive	-	List B
Jka-coom-02 Jka-coom-05	Anti-Jk ^a coombsreactive	-	List B
Jkb-coom-02 Jkb-coom-05	Anti-Jk ^b coombsreactive	-	List B
Jka-mono-MS15-02 Jka-mono-MS15-05	Anti-Jk ^a MS15	MS-15	List B
Jkb-mono-MS8-02 Jkb-mono-MS8-05	Anti-Jk ^b MS8	MS-8	List B
AHG-green-Ka-10	AHG polyspez.-rabbit	-	List B

Self declared other products

REF / Catalogue No.	Product designation	Clone	Classification
A1-Lekt-05 A1-Lekt-10	Anti-A1 Lectine	-	other products
Cw-mono-MS110-02 Cw-mono-MS110-05	Anti-C ^w MS110	MS-110	other products
Cw-inco-02 Cw-inco-05	Anti-C ^w incomplete	-	other products
Dia-coom-02	Anti-Dia coombsreactive	-	other products
H-mono-1093-05 H-mono-1093-10	Anti-H (A2) 10934C11	10934C11	other products
H-Lekt-05 H-Lekt-10	Anti-H (A2) Lectine	-	other products
cellano-coom-02 cellano-coom-05	Anti-k cellano coombsreactive	-	other products
Kpa-coom-02	Anti-Kp ^a coombsreactive	-	other products
Kpb-coom-02	Anti-Kp ^b coombsreactive	-	other products
KontRea-inko-10	Control reagent incomplete	-	other products
KontRea-mono-10	Control reagent monoclonal	-	other products
Lea-mono-LEA-02 Lea-mono-LEA-05	Anti-Le ^a LEA2	LEA2	other products
Leb-mono-LEB-02 Leb-mono-LEB-05	Anti-Le ^b LEB2	LEB2	other products
Lua-coom-02	Anti-Lu ^a coombsreactive	-	other products
Lub-coom-02	Anti-Lu ^b coombsreactive	-	other products
M-mono-11H2-02 M-mono-11H2-05	Anti-M 11H2	11H2	other products
N-mono-1422-02 N-mono-1422-05	Anti-N 1422C7	1422C7	other products
P1-mono-650-02 P1-mono-650-05	Anti-P1 650	650	other products
S-mono-MS94-02 S-mono-MS94-05	Anti-S MS94	MS-94	other products
S-coom-02 S-coom-05	Anti-S coombsreactive	-	other products
s-mono-P3BER-02 s-mono-P3BER-05	Anti-s P3BER	P3BER	other products
s-coom-02 s-coom-05	Anti-s coombsreactive	-	other products
Wra-coom-02	Anti-Wr ^a coombsreactive	-	other products
Xga-coom-02	Anti-Xg ^a coombsreactive	-	other products
IgG-coom-10	Anti-IgG monospez. Sheep	-	other products

AlseLö-500	Alsever's solution	-	other products
AlbuLi-10	Albu-LISS reagent	-	other products
Liss-10	LISS reagent	-	other products
BromLö-10	Bromelin solution	-	other products
BromKo-10	Bromelin-control reagent	-	other products
RA22%-10	Bovine albumin 22%	-	other products
RA30%-10	Bovine albumin 30%	-	other products